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UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	**Chapter 11**
PURDUE PHARMA L.P., *et al.*,	**Case No. 19-[ ] (RDD)**
Debtors.[1]	**(Joint Administration Pending)**

DEBTORS' INFORMATIONAL BRIEF

[1] The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF L.P. (0495), SVC Pharma L.P. (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

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I. Introduction

Purdue Pharma L.P. ("**Purdue Pharma**") and its subsidiaries that are debtors in possession in the above-captioned chapter 11 cases (collectively, "**Debtors**" or "**Purdue**")[2] are pharmaceutical companies that manufacture, sell, or distribute, among other products, extended-release, long-acting, abuse-deterrent opioid pain medications. OxyContin® Extended-Release Tablets CII ("**OxyContin**"), Purdue Pharma's most prominent pain medication, has been the target of over 2,600 civil actions pending in various state and federal courts and other fora across the United States and its territories ("**Pending Actions**"). These Pending Actions name as defendants Purdue Pharma and certain of the other Debtors ("**Defendant Debtors**"), among other parties, and generally allege that the Defendant Debtors falsely and deceptively marketed OxyContin and opioid pain medications, and are liable for the national opioid crisis.

Unlike most debtors, the Debtors have no funded debt and no material past due trade obligations. Nor do they have any judgment creditors.[3] Nonetheless, the onslaught of lawsuits has proved unmanageable and poses a grave threat to the Debtors' continued viability. Indeed, although the Debtors have contested – and continue to contest – their liability in the Pending Actions, continued litigation of thousands of Pending Actions to judgment and through appeals in the civil tort system will benefit no one; it will result only in the financial and operational destruction of the Debtors and the immense value they could otherwise provide, and the squandering of hundreds of millions of dollars on lawyers' and professionals' fees. Purdue Pharma, the Debtors' main operating entity, is projected to spend approximately $263 million on

[2] The terms "Debtors" and "Purdue" also include Purdue Pharma's general partner, Purdue Pharma Inc., discussed in Section II.B, *infra*.

[3] In fact, the only two cases litigated to final judgment – one in North Dakota and another in Connecticut – both resulted in dismissals as a matter of law on substantive grounds in favor of the Defendant Debtors. *See Order Granting Mot. to Dismiss, State of North Dakota ex rel. Wayne Stenehjem v. Purdue Pharma L.P., et al.*, No. 08-2018-CV-01300 (N.D. Dist. Ct. Burleigh Cty. May 10, 2019); *City of New Haven v. Purdue Pharma L.P.*, No. X07 HHD CV 17 6086134 S, 2019 WL 423990 (Conn. Super. Ct. Jan. 8, 2019).

legal and related professional costs in 2019, the vast bulk of which is related to the litigations and government investigations, and the financial pressure resulting therefrom. Indeed, by even the narrowest measure, Purdue Pharma has spent $63 million in the first half of this year on costs and fees related to litigating the Pending Actions in court, and is projected to spend $121 million by year end – a rate of over $2 million per week. Moreover, "Copycat" complaints are being filed against the Defendant Debtors by the day, further exacerbating an already untenable situation.

In addition, case-by-case mass tort litigation of the type the Defendant Debtors currently face in the civil tort system is neither an efficient, nor an equitable, way to resolve their alleged liability. Such litigation has only incentivized a multiplicity of "races to the courthouse" as various plaintiffs vied to be the first to trial – and employed ever more aggressive and creative means to that end. Several states even commenced administrative proceedings seeking dozens of trial days to bypass the normal court process and expedite the time to a final determination of their claims. This kaleidoscope of piecemeal litigation was and is all but guaranteed to continue to result in inconsistent outcomes and inequitable treatment, as well as unsustainable cost. Any judgments or settlements extracted in the process would, at best, potentially have benefited only those select few plaintiffs who happen to be positioned at the beginning of the trial and judgment queue. And it would not have benefited even them, because defending over 2,600 lawsuits to conclusion would almost certainly have forced the Defendant Debtors to file for chapter 11 protection even had they suffered only a small number of significant adverse judgments at the trial level. In its Supreme Court filing, the state of Arizona articulated the problem at hand: "Absent resolution in a single forum, these disputes will be fought over and over in nearly every

state in the Nation. This is likely to take years, lead to inconsistent judgments, and create an inequitable distribution of money damages."[4]

There is a better way. After a year of intense and arduous negotiations, the Debtors, the Debtors' ultimate owners (trusts for the benefit of members of the Sackler families ("**Sackler Families**")), and a critical mass of plaintiff constituencies have reached an agreement in principle on the structure of a global resolution of the Pending Actions ("**Settlement Structure**") – one that can be finalized and effectuated only through chapter 11. The plaintiff constituencies supporting the Settlement Structure include 24 state attorneys general and analogous officials from five U.S. territories,[5] as well as the court-appointed Plaintiffs' Executive Committee ("**PEC**") and Co-Lead Counsel in the federal multidistrict litigation pending in Ohio ("**Ohio MDL**"), which comprises attorneys at law firms that collectively represent over 1,000 counties, municipalities, Native American tribes, individuals, and third-party payors.

While there are many open points to be further refined and resolved, the Settlement Structure has three key basic components: As part of a resolution of the litigation, (1) Purdue's existing shareholders will relinquish all of their equity interests in the Debtors and consent to the transfer of all of the Debtors' assets to a trust or similar post-emergence structure for the benefit of claimants and the U.S. public, "free and clear" of Purdue's liabilities to the fullest extent permitted by law; (2) Purdue's existing shareholders will engage in a sale process for their ex-U.S. pharmaceutical companies; and (3) Purdue's existing shareholders will contribute an additional $3 billion over seven years (in addition to 100% of the value of all 24 Debtors), with

[4] *See* Br. in Supp. of Mot. for Leave to File Bill of Compl., at 20, No. 22O151, *State of Arizona v. Richard Sackler* (U.S., July 31, 2019).

[5] The states that have agreed to support the Settlement Structure include Alabama, Alaska, Arizona, Arkansas, Florida, Georgia, Indiana, Kansas, Louisiana, Michigan, Mississippi, Missouri, Montana, Nebraska, New Mexico, North Dakota, Ohio, South Carolina, South Dakota, Tennessee, Texas, Utah, West Virginia, and Wyoming. The five territories and/or commonwealths that have agreed to support the Settlement Structure include American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands.

the hope of substantial further contemplated contributions from the sales of their ex-U.S. pharmaceutical businesses.

The Debtors are hopeful that the Settlement Structure will allow their expertise and knowledge, intellectual property and manufacturing capacity to be put to positive healthcare uses for the American people. For example, "NewCo" intends to deploy its revenues and capabilities to produce and distribute (at no or low cost) millions of doses of opioid overdose reversal medications and a generic version of a leading addiction treatment medication. This proposal – which the Debtors hope and believe can be life saving – is unprecedented in scope and nature, and can be consummated only in connection with a resolution of the litigation.

While the Debtors have made important progress in recent weeks and months, they have learned through the negotiations that achieving a truly global consensual resolution of mass tort litigation in the civil tort system on the scale faced by the Defendant Debtors is not achievable. Plaintiffs (who include state attorneys general, counties, cities, towns, Native American tribes, third-party payors, hospitals, individuals, and others) have diverse interests that are sometimes overlapping and sometimes inconsistent. All the while, the Defendant Debtors continue to be besieged by an ever-increasing number of lawsuits that continue to deplete their estates.

The Debtors have commenced these chapter 11 proceedings because bankruptcy is the only way to resolve the litigation rationally; halt the destruction of value and runaway costs associated with the Pending Actions; centralize all of the claims against the Defendant Debtors; adjudicate the claims asserted against them fairly and efficiently; and, hopefully, expand the scope of parties supporting the Settlement Structure and consummate a global resolution of the Pending Actions – all while conserving the assets of the Debtors' estates so that billions of dollars in value and vital opioid overdose rescue medications can be delivered to communities

across the country impacted by the opioid crisis. This case will present unique challenges and require the Court and parties to navigate uncharted legal waters. But the Debtors believe that by working together with relevant stakeholders under this Court's direction, the parties can achieve a groundbreaking outcome that contributes meaningfully to the fight against the opioid crisis.

Bankruptcy is the only forum that provides a collective process that ensures equal treatment of similarly situated claimants and the finality that is essential to any comprehensive settlement. These attributes will, in turn, hopefully spur productive further discussions with those plaintiffs who currently oppose the Settlement Structure. If not, a unique opportunity to benefit Americans in need with billions of dollars of products, assets, and cash – as an alternative to years of litigation and value destruction – may be lost.

Utilizing bankruptcy in this manner, on these facts, requires resolution of an important threshold issue, present here because the vast majority of lawsuits against the Defendant Debtors – over 85% by number – have been brought by governmental plaintiffs. Unlike typical mass tort cases in which the automatic stay virtually always protects the debtor from having to continue to expend resources litigating actions outside of bankruptcy, the Debtors anticipate that many or all of the governmental plaintiffs who have not agreed to support the Settlement Structure will claim that their actions are exempt from the automatic stay by virtue of the section 362(b)(4) police and regulatory power exception.[6]

[6] The Attorney General of Ohio has filed a petition for a writ of mandamus seeking to halt claims brought by political subdivisions of Ohio on the ground that "only Ohio, not its counties, has the power and the right to represent the people of the State." Pet. for Writ of Mandamus of State of Ohio (Dkt. No. 1), *In re State of Ohio*, No. 19-3827 (6th Cir. Aug. 30, 2019). The Attorneys General of thirteen states and the District of Colombia filed a brief of *amici curiae* supporting the Ohio Attorney General, arguing that "smaller political subdivisions lack the broad powers and duties that are necessary to effectively protect the States' citizenry as a whole." Br. of Amici Curiae of Michigan, Alaska, Arizona, Connecticut, Hawaii, Indiana, Kansas, Montana, Nebraska, North Dakota, South Dakota, Tennessee, Texas, and the District of Columbia in Supp. of the State of Ohio's Pet. For Writ of Mandamus (Dkt. No. 7), *In re State of Ohio*, at 13, No. 19-3827 (6th Cir. Sept. 6, 2019).

In anticipation of this, the Defendant Debtors will soon commence an adversary proceeding and file a motion for a preliminary injunction ("**Preliminary Injunction Motion**") to enjoin the continued prosecution of the active governmental litigation against the Defendant Debtors, to the extent that section 362(a) does not apply, pursuant to section 105(a) of the Bankruptcy Code. In connection with this motion, the Debtors intend to seek an unprecedented voluntary injunction against themselves that will address the past conduct complained of in the Pending Actions. The Debtors will request this relief to put beyond any doubt that they are not attempting to frustrate governmental functions by "seeking refuge" in bankruptcy court. Moreover, because claims against current and former owners, officers, directors, employees, and entities associated with the Defendant Debtors ("**Related Parties**") are inextricably intertwined with and related to the claims against the Defendant Debtors, the Defendant Debtors will also ask this Court to enjoin active litigation against those parties.

Protection from uncontrolled litigation is the singular feature of bankruptcy that makes it an effective tool for the successful resolution of mass tort matters. Absent that protection, this case will fail because the fundamental goal of this and any bankruptcy will have been thwarted: the centralized, efficient and rational resolution of claims against the Debtors and the fair distribution of the Debtors' assets at the lowest possible cost – hopefully accomplished here by effectuating the consensual resolution reflected in the Settlement Structure. The Debtors' estates will be depleted by the blows they continue to take, and the hundreds of millions of dollars in annual legal fees that would otherwise be available to help address opioid overdoses will have been lost; the plaintiffs' jockeying and race to many courthouses will continue; coordinated negotiation of a global settlement will be all but impossible; the plaintiffs will inevitably be

subject to disparate litigation outcomes; and any prevailing tort claimants will be unable to enforce their money judgments against the Defendant Debtors in any event.

The requested injunctions are needed to provide what virtually every other debtor in chapter 11 has gotten automatically and immediately – a juridical space designed to enable them to craft and implement a value-maximizing, and hopefully consensual, resolution that will inure to the benefit of the American public.

* * *

The Debtors submit this informational brief ("**Brief**") to provide relevant background information to the Court and parties in interest. This Brief first sets forth background information about the Debtors, including information concerning the medications that they manufacture, sell, or distribute. Then, it explains why the Debtors have been forced to resort to chapter 11 to help define and resolve the claims against them. Finally, although the Debtors are not now seeking any relief with respect to future procedures in this case, the Brief provides the Debtors' vision for how the case might proceed to a successful conclusion.

II. The Debtors, the Debtors' Corporate Structure, and the Debtors' Business

Purdue operates three main business segments through a number of operating subsidiaries: a branded prescription medication business, a generic prescription medication business, and an over-the-counter medication business. In addition, as part of its commitment to advancing meaningful solutions to the opioid crisis, Purdue continues to develop, and plans to distribute on a nonprofit basis, opioid overdose reversal and addiction-treatment medications ("**Public Health Initiative**"). The Debtors are managed by a single board of directors and are wholly owned by the same ultimate owners: various trusts for the benefit of the descendants of Mortimer and Raymond Sackler.

This section provides background information on the Debtors' corporate structure and these various business segments.

A. Purdue Pharma L.P. and Purdue Subsidiaries

Purdue Pharma L.P., a Delaware limited partnership headquartered in Stamford, Connecticut, is the Debtors' main operating entity. Purdue Pharma's general partner is Purdue Pharma Inc. ("**PPI**"). Purdue Pharma also has 22 wholly owned operating and nonoperating subsidiaries in the United States and the British Virgin Islands ("**Purdue Subsidiaries**"). An organizational chart setting forth this corporate structure is provided in Appendix A.

1. Branded Prescription Medication Business

Purdue's branded prescription pharmaceutical business, operated by Purdue Pharma, consists of both opioid and non-opioid medications. Purdue Pharma's three principal branded opioid medications are OxyContin®, Hysingla ER®, and Butrans®:

- OxyContin Extended Release Tablets: OxyContin (discussed in more detail in Section V.A, *infra*) is a Schedule II extended-release, long-acting opioid analgesic. Its active pharmaceutical ingredient ("**API**") is oxycodone.[7] OxyContin received Food and Drug Administration ("**FDA**") approval in 1995 and was launched in 1996. In 2010, the FDA approved, and Purdue began selling, a new abuse-deterrent formulation of OxyContin.

- Hysingla ER Extended Release Tablets: Hysingla ER is a Schedule II extended-release, long-acting, abuse-deterrent opioid analgesic. Its API is hydrocodone. Hysingla ER was approved by the FDA in 2014 and was launched in 2015.

- Butrans Transdermal System: Butrans is a Schedule III,[8] seven-day, transdermal patch pain medication. Its API is buprenorphine.[9] Butrans was approved by the FDA in 2010 and launched in 2011.

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[7] *See* U.S. Food and Drug Admin., OxyContin Full Prescribing Information, at 1 (Sept. 26, 2018), https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022272s039lbl.pdf (hereinafter "OxyContin FPI").

[8] Schedule III drugs are defined as "drugs with a moderate to low potential for physical and psychological dependence," according to the U.S. Drug Enforcement Administration ("**DEA**"). *See* U.S. Drug Enf't Admin., Drug Schedule (last visited Sept. 15, 2019), https://www.dea.gov/drug-scheduling.

[9] *See* U.S. Food and Drug Admin., Butrans Full Prescribing Information, at 1 (Sept. 18, 2018), https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021306s032s034lbl.pdf (hereinafter "Butrans FPI").

Purdue Pharma manufactures OxyContin and Hysingla for itself and, in relatively limited amounts, manufactures OxyContin for certain foreign independent associated companies ultimately owned by the Sackler Families ("**Foreign IACs**"). Purdue Pharma also receives royalties from Foreign IACs for sales of OxyContin outside the United States. In the first half of 2019, Purdue Pharma's share of total prescriptions dispensed from retail pharmacies in the United States for opioid pain medications was 1.5%.

In addition to prescription opioid medications, Purdue Pharma sells, through a subsidiary, a non-opioid branded prescription medication for the management of attention deficit hyperactivity disorder. Purdue Pharma has also invested – and continues to invest – substantial resources in the development of oncology medications to address difficult-to-treat blood cancers, solid cancers, and central nervous system cancers. Other pipeline drugs include a novel non-opioid epidural steroid injection for the treatment of lower back pain, medications to treat insomnia related to alcohol cessation, and non-opioid treatments for neuropathic (nerve) pain and interstitial cystitis (bladder) pain.

2. Generic Prescription Medication Business / API Business

(a) Rhodes Pharmaceuticals L.P.

Purdue's generic prescription pharmaceutical business is operated by Purdue subsidiary Rhodes Pharmaceuticals L.P. ("**Rhodes Pharma**"), a Delaware limited partnership created in late 2007. Rhodes Pharma, which until May 2019 was separately managed from Purdue, *see* Section II.A.2(c), *infra*, sells a variety of generic prescription medications, including opioid (principally immediate-release) pain relievers.[10] Rhodes Pharma does not have – and never has

[10] Starting in 2017, Purdue Pharma authorized Rhodes Pharma to sell an authorized generic of Butrans (opioid transdermal patch) in exchange for a profit share. Rhodes Pharma's authorized generic Butrans has been sold as a generic product and never promoted to prescribers or patients. Moreover, although Rhodes Pharma's portfolio of products is composed mostly of generic products, in 2015, Rhodes Pharma expanded into a branded prescription product, Aptensio XR, a once-daily extended-release central nervous system stimulant (methylphenidate) indicated

had – sales representatives promote or market its opioid drugs to prescribers or patients. From 2012 to 2018, Rhodes Pharma's market share of total opioid prescriptions was 0.9%, 1.4%, 1.5%, 2.6%, 4.1%, 5.6%, and 7.5%, respectively. From 2008 to 2012, Rhodes Pharma accounted for less than 1% of the market. In the first half of 2019, Rhodes Pharma's share of the total prescriptions dispensed from retail pharmacies in the United States for opioid pain medications was 9.1%.

Rhodes Pharma also sells generic non-opioid medications, such as medications to treat attention deficit hyperactivity disorder, high cholesterol, and depression. Rhodes Pharma does not manufacture any of its generic prescription offerings. Rather, a Purdue subsidiary and other non-Purdue entities manufacture finished dosage forms for Rhodes Pharma.

(b) Rhodes Technologies

Rhodes Technologies ("**Rhodes Tech**"), a Delaware general partnership, is also a Purdue subsidiary (as of May 2019) and debtor in this case. Rhodes Tech manufactures active pharmaceutical ingredients – known as APIs – that Purdue Pharma uses to manufacture its branded finished products and some of Rhodes Pharma's generic finished products. Rhodes Pharma and Rhodes Tech are defendants in more than 700 of the Pending Actions.

(c) Until Recently, the Rhodes Entities Have Been Managed Separately

Prior to 2008, Rhodes Tech (or its predecessor) was a subsidiary of Purdue Pharma. On or around January 1, 2008, Rhodes Tech was moved to a different Sackler Families ownership chain (through Purdue Pharma's distribution of its interest in Rhodes Tech's parent to an affiliate). Rhodes Tech then came under common ownership with newly created Rhodes

for the treatment of attention deficit hyperactivity disorder. Additionally, since 2017, Rhodes Pharma has sold MS Contin and Dilaudid branded opioid pain medications, which were contributed to Rhodes Pharma by Purdue. Rhodes Pharma has never promoted any Dilaudid or MS Contin product to prescribers or patients.

Pharma. Until May 2019, Rhodes Pharma and Rhodes Tech were separately managed by different boards of directors from that of Purdue Pharma.[11] The ultimate owners of these Rhodes entities, however, have always been the same as Purdue's – various trusts for benefit of the Sackler Families.

In May 2019, Rhodes Pharma and Rhodes Tech were contributed to Purdue Pharma, becoming subsidiaries of Purdue. Thus, from and after that date, PPI effectively managed Rhodes Pharma and Rhodes Tech. This reorganization was undertaken, among other reasons, to achieve cost and operational efficiencies and so that a single board and management team would be at the helm of the U.S. pharmaceutical businesses in order to, among other things, help facilitate a complex settlement process, including one that potentially could be implemented through chapter 11.

3. Over-the-Counter Medication Business

Avrio Health L.P. ("**Avrio**"), a Delaware limited partnership and also a Purdue subsidiary, is headquartered in New York City and operates the Debtors' over-the-counter ("**OTC**") medications business.[12] OTC medications are FDA-regulated but do not require prescriptions. Avrio has no role in Purdue's branded or generic prescription medication business.

[11] Prior to May 2019, some Rhodes Pharma and Rhodes Tech directors served as directors or officers of Purdue Pharma.

[12] Avrio engages in the marketing, sale, and distribution of four principal and well known OTC medications: Betadine (an antiseptic that Purdue's predecessor developed 50 years ago for use at home and in hospitals, and which is an important defense against topical infections; Colace and Peri-Colace, now called Colace 2-IN-1 (stool softeners and stool stimulants to treat occasional constipation); Senokot (a laxative for occasional constipation); and SlowMag (a magnesium supplement with high-absorption magnesium chloride plus calcium).

4. Public Health Initiatives: Opioid Overdose Reversal and Addiction Treatment Medications

As part of its commitment to advance meaningful solutions to the opioid crisis, Purdue is developing products designed to reverse opioid overdoses and treat opioid addiction.

First, Purdue is developing a new emergency opioid overdose treatment containing the opioid antagonist nalmefene.[13] Emergency opioid overdose rescue drugs, when timely administered, can quickly restore normal respiration to a person whose breathing has slowed or stopped as a result of overdosing with a prescription or illicit opioid.[14] As discussed more fully below, synthetic opioids, such as illicit fentanyl and its analogues, are a principal driver of today's epidemic of opioid overdose deaths. But existing opioid overdose reversal medications may not be sufficiently potent or long-lasting to reverse the effects of fentanyl (which is 50 times more potent than heroin), requiring multiple doses to attempt to rescue a patient.

To address this need, Purdue is developing an opioid overdose reversal medication containing nalmefene,[15] a high-potency, long-acting opioid antagonist, for application in three different injectable forms: a vial and pre-filled syringe for administration by first responders and healthcare providers, and an autoinjector for administration by friends, family, and caregivers. In February of this year, the FDA granted Purdue's injectable nalmefene product "Fast Track" status. Fast Track is a formal designation by the FDA to expedite review and facilitate development of new drugs that the FDA determines are intended to treat a serious or life-threatening condition and fulfill an unmet medical need. Purdue has been advocating for a

[13] Opioid antagonists bind to block the activation of opioid receptors. *See* Nat'l Inst. on Drug Abuse, Medications to Treat Opioid Use Disorder (June 2018), https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/how-do-medications-to-treat-opioid-addiction-work.

[14] *See* U.S. Nat'l. Inst. on Drug Abuse, Opioid Overdose Reversal with Naloxone (Narcan, Exvio) (Apr. 2018), https://www.drugabuse.gov/related-topics/opioid-overdose-reversal-naloxone-narcan-evzio.

[15] A prior version of nalmefene was previously approved by the FDA and withdrawn for reasons other than safety.

settlement that would ensure that the development of this rescue medication is completed and that the settlement is structured so that millions of doses can be distributed at no or low cost to communities across America.

Second, Purdue is aiding the development of a low-cost, OTC naloxone nasal spray to reverse a suspected opioid overdose. Although intranasal naloxone is currently available to consumers under the brand name Narcan®, access is limited because of Narcan's relatively high cost to consumers and first responders, and because of the requirement that consumers obtain this prescription medication from a pharmacist, i.e., from "behind the counter." To help overcome these barriers to access, Purdue is working with Harm Reduction Therapeutics ("**HRT**"), an independent pharmaceutical company seeking nonprofit status, to develop a low-cost OTC naloxone nasal spray. By reducing the cost and allowing consumers to acquire the medication online from retail outlets or from a pharmacy without the fear of the stigma that often comes with speaking to a pharmacist, Purdue hopes to greatly improve access to this needed medication. To facilitate this, Purdue has paid, and plans to continue paying, for HRT's development costs. Purdue has also licensed valuable technical know-how and data and provided regulatory and drug-development advice. Purdue intends to distribute millions of doses of this product at low or no cost to communities around the country to help them combat the opioid crisis.

Third, Purdue, through Rhodes Pharma, is seeking FDA approval for a generic version of Suboxone® tablets, a leading opioid addiction treatment consisting of buprenorphine and naloxone. Patients with opioid addiction need treatment but often cannot afford it. To address this need, Purdue intends to distribute millions of doses of this valuable treatment at low or no cost.

B. Purdue Pharma Inc.

PPI is the general partner of Purdue Pharma, and the board of directors of PPI ("**Board**") effectively manages the Debtors.[16]

1. PPI's Board of Directors

The Board is currently composed of seven directors, five of whom became members in approximately the last year. Under PPI's shareholder agreement, shareholder entities ultimately owned by the descendants of Mortimer Sackler have the right to appoint up to two "Class A Directors," and shareholder entities ultimately owned by the descendants of Raymond Sackler have the right to appoint up to two "Class B Directors." Finally, the shareholders jointly appoint a Board chair and additional "At-Large Directors." PPI's current directors are provided in the following chart:

Director	Date Appointed	Title
Robert S. "Steve" Miller	July 2018	**Chairman of the Board**
Kenneth Buckfire	May 2019	**At-Large Director**
John S. Dubel	July 2019	**At-Large Director**
Michael Cola	July 2019	**At-Large Director**
Anthony Roncalli	December 2018	**Class B Director**
Cecil Picket, Ph.D.	January 2010	**Class A Director**
F. Peter Boer, Ph.D.	April 2008	**Class B Director**

[16]As illustrated in Appendix A, the Purdue Subsidiaries have PPI as a general partner, are indirectly controlled by PPI pursuant to PPI's being a general partner of another Purdue subsidiary, or have Purdue Pharma, directly or indirectly, as their ultimate sole shareholder.

PPI's current slate of directors is noteworthy for at least two reasons. First, four of the directors – Messrs. Miller, Cola, Buckfire, and Dubel, each of whom has no prior relationship with the Debtors[17] – collectively bring to the Board many decades of restructuring or pharmaceutical business experience that will be indispensable in steering the Debtors through this complex bankruptcy. PPI's three other directors – one with a Ph.D. in cell biology, another with a Ph.D. in chemical physics, and one with a J.D. – have extensive and invaluable pharmaceutical experience and decades of company knowledge. Second, although various members of the Sackler Families have previously served on the Board, no member of the Sackler Families currently serves as a director or employee. Thus, a majority of the Board has no prior connection to the Sackler Families, and three of the directors are well known to many in the U.S. restructuring community with more than 100 years of collective experience.

2. Committees of the Board

One committee of the Board, the Special Committee ("**Special Committee**"), will continue to be central to the Debtors' successful reorganization efforts and merits specific mention. Under PPI's Shareholder Agreement, the Special Committee is required to approve, and has full delegated authority with respect to, <u>all</u> matters between the Debtors, on the one hand, and any member of the Sackler Families or any of their affiliates, on the other. The Special Committee also has authority with respect to all litigation matters between the Debtors, on the one hand, and any member of the Sackler Families or any of their affiliates, on the other. Directors Miller, Buckfire, Dubel, and Cola are the sole members of the Special Committee. No Class A Directors or Class B Directors serve on the Special Committee.

[17] Mr. Cola was, in 2013, briefly considered for the role of president and CEO of Purdue Pharma, and had no further contact with the Debtors or the Sackler Families until contacted by a headhunter about a possible role on PPI's Board.

The Debtors and the Board take very seriously the asserted claims relating to the Sackler Families' prepetition management of the Debtors, and the Debtors' historical distributions to their owners. The Special Committee has been overseeing various investigations, including an exhaustive review by outside experts of distributions made by the Debtors to the Sackler Families and their affiliates, as well as any dealings between the Debtors and any member of the Sackler Families or any of their affiliates. This important work is ongoing; professionals at AlixPartners LLP, Bates White, and Davis Polk & Wardwell LLP have dedicated more than 12,000 hours to these projects to date at the direction and under the supervision of the Special Committee, which, in the past months, has been meeting multiple times each month on these issues.

C. Ownership of the Debtors

Purdue is wholly owned by Pharmaceutical Research Associates L.P. ("**PRA**"), a Delaware limited partnership. PRA is not a debtor in this case.

PRA is ultimately 99.5% owned by two entities in equal part, Beacon Company ("**Beacon**"), a Delaware general partnership, and Rosebay Medical Company L.P. ("**Rosebay**"), a Delaware limited partnership. Neither of these two entities is a debtor. Beacon and Rosebay are ultimately owned by various trusts established for the benefit of the Sackler Families.

The remaining equity interest in PRA (approximately 0.5%) is owned in approximately equal parts by PPI (as noted above) and PLP Associates Holdings Inc. ("**PLP**"), a New York corporation. PLP is not a debtor. PPI and PLP are also ultimately owned by various trusts established for the benefit of members of the Sackler Families. Under PPI's Amended and Restated Shareholders Agreement, PPI is not allowed to directly or indirectly: (1) own more than 1% of the equity interests in any entity other than Purdue Pharma; (2) be a general partner of any entity or have any voting or governance interests in any entity other than Purdue Pharma

or any subsidiary of Purdue Pharma; and (3) engage in any business or activity, except serving as the general partner of Purdue Pharma and any of its subsidiaries, in each case without the approval of PPI's shareholders.

III. Opioid Medications in General

As discussed above, Purdue makes and sells opioid pain medications. One of these products, OxyContin, has been a particular focus of the Pending Actions and the press.

The term "opioids" covers a broad class of drugs, both legal and illegal. It includes natural opioids, which are derived from the opium poppy plant (e.g., morphine and codeine); semi-synthetic opioids, which are synthesized from naturally occurring opium products (e.g., oxycodone and hydrocodone as well as heroin); and synthetic opioids, which are made entirely in the laboratory (e.g., both prescription and illicit fentanyl).[18] Under the Controlled Substances Act, 21 U.S.C. § 801. ("**CSA**"), the DEA classifies – or "schedules" – legal and illegal opioids according to their abuse potential.[19] Schedule I drugs, which are illegal, are drugs with "no currently accepted medical use and a high potential for abuse."[20] Heroin is a Schedule I drug. Unlike Schedule I drugs, Schedule II drugs can be used for a legitimate medical purpose but have a "high potential for abuse" which may lead to "severe psychological or physical dependence."[21] Most opioid pain medications are Schedule II drugs, including FDA-approved

[18] *See* U.S. Drug Enf't Admin., Narcotics (Opioids) (last visited Sept. 15, 2019), https://www.dea.gov/taxonomy/term/331.

[19] *See* U.S. Drug Enf't Admin., Drug Schedule (last visited Sept. 15, 2019), https://www.dea.gov/drug-scheduling. Non-opioid drugs can also be DEA-scheduled. Examples include Adderall, Ritalin, testosterone, Xanax, Valium, and Ambien.

[20] *See id.*

[21] *See id.*

morphine, methadone, oxycodone, hydrocodone, and fentanyl products.[22] Doctors must register with the DEA in order to prescribe Schedule II drugs.[23]

Opioid medications can vary in dosage form, such as a tablet, patch, or oral solution.[24] They may also be combined with a non-opioid pain medication, such as acetaminophen, to form a combination product (examples are Vicodin® and Percocet®).[25] The overwhelming majority of prescribed opioid medications are immediate-release, and typically require dosing four to six times per day.[26] Others, however, are formulated to release the opioid over time (known as extended-release, sustained-release, or controlled-release formulations), allowing for less frequent daily dosing. Patch products may require dosing even less frequently – e.g., Purdue's Butrans patch lasts seven days.[27]

Opioid medications are and continue to be recognized by the FDA, and prescribed by the medical community, as safe and effective medications for the management of certain categories

[22] There are three other schedules. Schedule III drugs are drugs with "a moderate or low physical dependence or high psychological dependence" with an abuse potential that is less than that of Schedule I and II drugs. Buprenorphine is an example of a Schedule III drug. Schedule IV drugs are defined as drugs with a "low potential for abuse relative to substances in Schedule III." Lorazepam is an example of a Schedule IV opioid. Schedule V drugs are defined as drugs with "low potential for abuse relative to substances listed in Schedule IV and consists primarily of preparations containing limited quantities of certain narcotics." Cough preparations with less than 200 mg of codeine per 100 ml are an example of a Schedule V drug. *See* U.S. Drug Enf't Admin., Drug Schedule (last visited Sept. 15, 2019), https://www.dea.gov/drug-scheduling; U.S. Drug Enf't Admin., Diversion Control Div., Controlled Substances Schedule (last visited Sept. 15, 2019), https://www.deadiversion.usdoj.gov/schedules.

[23] *See* U.S. Drug Enf't Admin., Practitioner's Manual: An Informational Outline of the Controlled Substances Act at 7 (2006 ed.), https://www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html.

[24] *See* OxyContin FPI, at 1; Butrans FPI, at 1; U.S. Food and Drug Admin., Dilaudid Full Prescribing Information, at 1 (Sept. 26, 2018), https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019891s026s027, 019892s033s034lbl.pdf.

[25] *See* U.S. Food and Drug Admin., Percocet Full Prescribing Information, at 1 (Nov. 2006), https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/040330s015,040341s013,040434s003lbl.pdf ; *see* U.S. Food and Drug Admin., Vicodin Full Prescribing Information, at 1 (Nov. 2006), https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/088058s027lbl.pdf.

[26] *See* Presentation, U.S. Food and Drug Admin., CDER, *Search for Balance: FDA's Approach to Opioids Crisis*, Douglas C. Throckmorton, MD Deputy Director for Regulatory Programs, at 8 (Presented at the Virginia Pain Society Meeting, Mar. 9, 2019), https://www.fda.gov/media/122423/download.

[27] *See* Butrans FPI, at 1.

of pain.[28] For example, opioids are, in appropriate circumstances, prescribed to manage pain resulting from surgeries and from trauma;[29] from certain medical conditions, such as sickle cell disease;[30] and pain associated with end-of-life care.[31] Opioid medications are also an important tool for the management of pain, which is a common symptom in cancer patients.[32] According to a peer-reviewed summary of medical literature undertaken by the National Cancer Institute, "[t]he use of opioids for the relief of moderate to severe cancer pain is considered necessary for most patients."[33] In fact, for severe cancer pain, strong opioids (such as oxycodone and morphine) are routinely used, and after acute pain is managed with immediate-release opioids, many patients are prescribed extended-release opioids[34] (such as OxyContin and extended-release morphine). Opioids may also be used to manage pain caused by cancer therapies, including surgery, radiation therapy, chemotherapy, and certain diagnostic procedures.[35]

Although opioid medications serve an important medical purpose, there can be no doubt that opioid medications, even when taken as prescribed, present risks of abuse, misuse, and

[28] *See* OxyContin FPI, at 1.

[29] *See* U.S. Dep't of Health & Human Servs., Pain Management Best Practices Inter-Agency Task Force Report 11 (May 9, 2019), https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf.

[30] *See* U.S. Nat'l Insts. of Health, Opioid Crisis Adds to Pain of Sickle Cell Patients (Sept. 15, 2017), https://www.nhlbi.nih.gov/news/2017/opioid-crisis-adds-pain-sickle-cell-patients.

[31] *See* U.S. Dep't of Health & Human Servs., Pain Management Best Practices Inter-Agency Task Force Report 69 (May 9, 2019), https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf.

[32] *See* U.S. Nat'l Cancer Inst., PDQ Supportive and Palliative Care Editorial Board, PDQ Cancer Information Summaries (Mar. 6, 2019), https://www.ncbi.nlm.nih.gov/books/NBK65949/?report=classic.

[33] *See id.*

[34] *See id.*

[35] *See* U.S. Nat'l Cancer Inst., Pain in People with Cancer (Aug. 9, 2018), https://www.cancer.gov/aboutcancer/treatment/side-effects/pain; *see also* American Cancer Society, *Opioids for Cancer Pain*, (Jan. 3, 2019), https://www.cancer.org/treatment/treatments-and-side-effects/physical-side-effects/pain/opioid-pain-medicines-for-cancer-pain.html.

addiction that can result in overdose, addiction, and death.[36] In the United States, misuse and abuse of opioids, including prescription pain medication, is a significant public safety concern.

IV. The Market for Prescription Opioids in the United States

The opioid prescription market in the United States is complex. It involves a highly regulated, multifaceted manufacturing and distribution system. That system involves a number of participants, such as pharmaceutical manufacturers, distributors, retailers, third-party administrators, pharmacy benefit management companies, managed care organizations, and providers.[37] There are, accordingly, multiple entities in the supply chain between the Debtors and end users of their prescription opioids.

Moreover, the FDA and the DEA regulate and enforce a multitude of regulations and laws across the distribution system. For example, the DEA enforces a congressionally mandated quota system controlling the supply of API in the United States used by manufacturers to produce opioid medications.[38] The CSA establishes a closed system by which the manufacture, distribution, importation, exportation, and use of controlled substances are always under legal authority of an entity registered with (or exempted by) the DEA until the controlled substance reaches the end user (i.e., patient) or is destroyed. To reduce or eliminate diversion from legitimate channels of trade, the DEA determines the annual need for each basic class of narcotic substance, including oxycodone (used to make OxyContin), according to various factors,

[36] *See id.*; *see also* OxyContin FPI at 1.

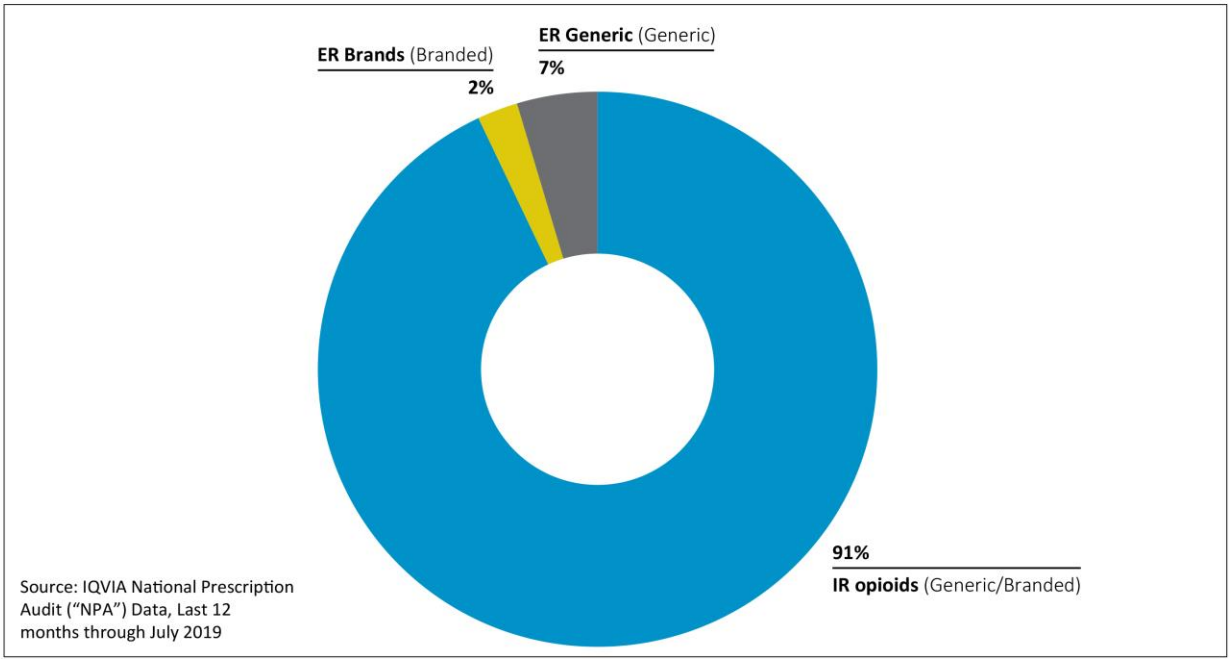
[37] *See* U.S. Dep't of Health and Human Servs., Report to the President: Prescription Drug Coverage, Spending, Utilization and Prices, 3.2 Drug Distribution Chain (Apr. 1, 2000), https://aspe.hhs.gov/report/report-president-prescription-drug-coverage-spending-utilization-and-prices/32-drug-distribution-chain.

[38] *See* Press Release, U.S. Drug Enf't Admin., Justice Department, DEA propose significant opioid manufacturing reduction in 2019 (Aug. 16, 2018), https://www.dea.gov/press-releases/2018/08/16/justice-department-dea-propose-significant-opioid-manufacturing-reduction; *see also* 21 U.S.C. § 826.

including medical need, and sets quotas applicable to, among other entities, manufacturers of pharmaceutical products containing such controlled substances.[39]

The U.S. prescription opioid market is primarily divided between extended-release and immediate-release opioid products.[40] Immediate-release opioids have always dominated the market. For example, over a recent twelve month period, as illustrated in the following figure, immediate-release opioid products accounted for an overwhelming majority – over 90% – of the prescriptions of opioid analgesics dispensed by retail pharmacies in the United States. By contrast, extended-release opioid products made up only about 10%. Branded extended-release opioid products, which include Purdue's OxyContin, Hysingla ER, and Butrans, made up yet a smaller percentage.

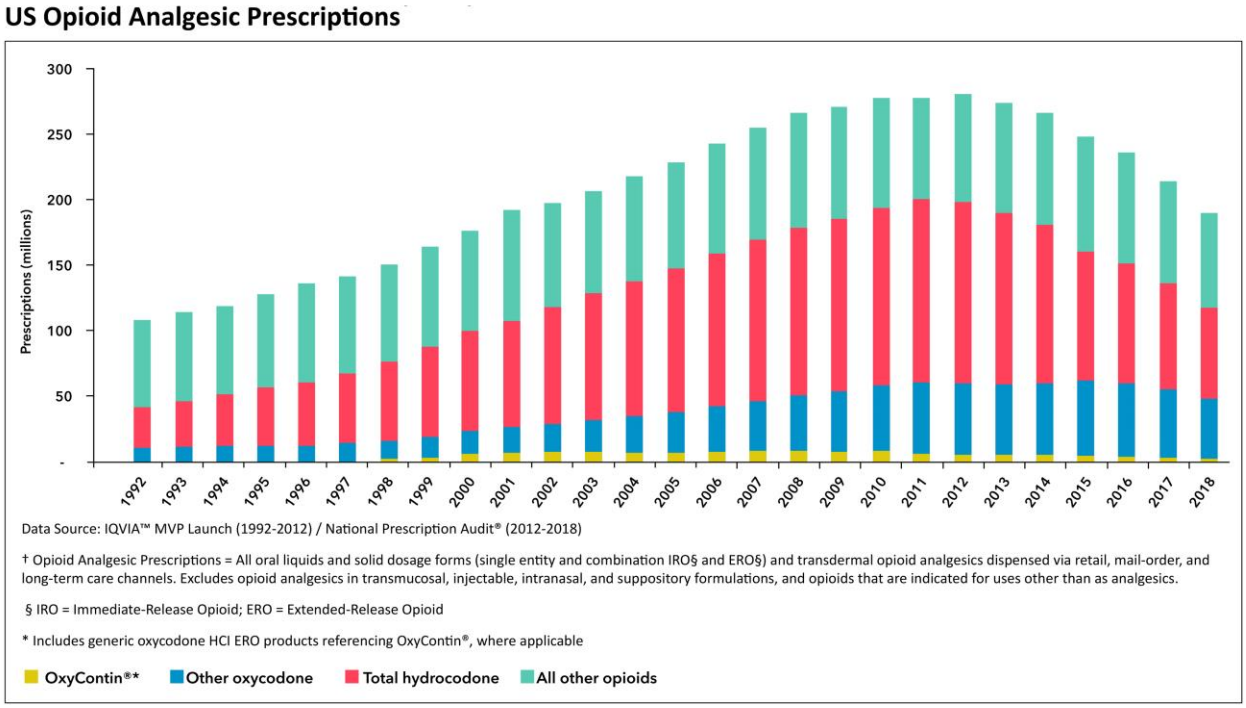
Total Opioid Prescription Market (2018-2019)



[39] *See* U.S. Dep't of Justice, Aggregate Production Quota History for Selected Substances (Jan. 22, 2019), https://www.deadiversion.usdoj.gov/quotas/quota_history.pdf.

[40] There is also a subclass of immediate-release opioids called transmucosal immediate-release fentanyl, or "TIRFs."

Notwithstanding that OxyContin's current market share is under 2%, and has never exceeded 4%, of opioid prescriptions (represented by the yellow bar at the very bottom in the chart below), OxyContin, in particular, has been a primary target of the Pending Actions.[41]



V. OxyContin

OxyContin is an effective pain medicine. Like all opioid medications, however, it carries with it associated risks of misuse, abuse, and addiction. The FDA, striking a balance between the need for such medications and their risks, approved OxyContin in December 1995 and approved the abuse-deterrent formulation in 2010. OxyContin remains approved today.

[41] *See, e.g.*, Suppl. Summons and First Am. Compl. ¶ 5, *People of State of New York v. Purdue Pharma L.P.*, No. 400016/2018 (N.Y. Sup. Ct. Suffolk Cty. Mar. 28, 2019) (alleging that "[t]he taproot of the opioid epidemic is easy to identify: OxyContin"); Summons and Am. Compl. ¶ 110, *State of Nevada v. McKesson Corp.*, No.: A-19-796755-B (Dist. Ct. Clark Cty.) (alleging that OxyContin's "launch in 1996 ushered in the modern opioid epidemic"); Compl. ¶ 2, *State of Oregon v. Richard Sackler*, No. 19-22815 (Cir. Ct. Multnomah Cty. May 16, 2019) (alleging that "[t]he drug [OxyContin] kicked off a nationwide epidemic"); First Am. Compl. ¶ 2, *Commonwealth of Massachusetts v. Purdue Pharma L.P.*, C.A. No. 1884-cv-01808 (Mass. Sup. Ct. Suffolk Cty. Jan. 31, 2019) (alleging that "Purdue Pharma created the epidemic").

A. OxyContin Is an Extended-Release Opioid Medication

OxyContin is currently indicated – i.e., approved – for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alterative treatment options are inadequate.[42]

OxyContin's API is oxycodone.[43] Although many sources conflate oxycodone with Purdue's medication, OxyContin, oxycodone comes in many forms, and has been available and marketed in the United States in an "immediate-release" formulation since the early 20th century, many decades before Purdue developed OxyContin.[44] Immediate-release opioid analgesics, however, require frequent daily dosing. Because they are short-acting, patients suffering from chronic severe pain who require around-the-clock opioid therapy may have to take them often – sometimes four to six times per day – which, among other things, can result in waking multiple times per night to take another dose of pain medication. Purdue's initial innovation in OxyContin was in developing an extended-release dosage form to deliver oxycodone over a 12-hour period.[45] The dosage form allows patients to reduce the number of doses required each day. OxyContin was the first oxycodone product that was approved by the FDA for twice-daily, every 12-hour, dosing.[46]

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[42] *See* OxyContin FPI, at 1.

[43] *See id.*

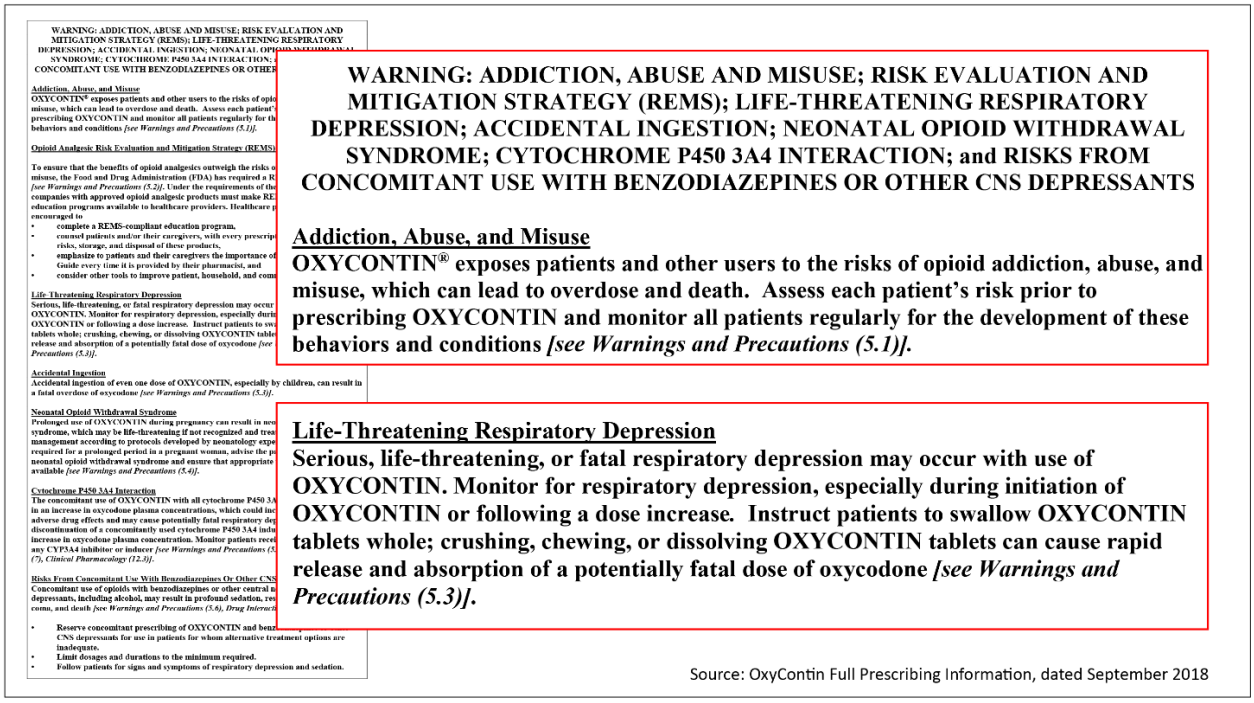
[44] *See* U.S. Nat'l Insts. of Health, Drug Record: Oxycodone (July 1, 2019), https://livertox.nlm.nih.gov/Oxycodone.htm.

[45] *See OxyContin: Balancing Risks and Benefits on Examining the Effects of the Painkiller OxyContin, Focusing on Federal, State and Local Efforts to Decrease Abuse and Misuse of This Product While Assuring Availability for Patients Who Suffer Daily From Chronic Moderate to Severe Pain Before the Comm. on Health, Education, Labor, and Pensions*, 107th Cong. Sess. 2 (Feb. 12, 2002) (Testimony of John K. Jenkins, Director, Office of New Drugs, Center for Drug Evaluation and Research, FDA), at 15-16 (hereinafter "February 2002 Senate Hearing").

[46] *See* U.S. Food and Drug Admin., Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse (May 30, 2019), https://www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-opioid-misuse-and-abuse (hereinafter "FDA Timeline").

OxyContin is designed to be taken only whole and only by mouth.[47] As OxyContin's label has always warned, if the OxyContin tablet were to be crushed, the controlled-release mechanism could be defeated and the oxycodone contained in the tablet could be released at once, creating a risk of serious injury or death.[48] OxyContin's current black box warning – the most prominent warning labeling mechanism for FDA-approved medications – sets forth these and other risks:

OxyContin Black Box Warning



WARNING: ADDICTION, ABUSE AND MISUSE; RISK EVALUATION AND MITIGATION STRATEGY (REMS); LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; CYTOCHROME P450 3A4 INTERACTION; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Addiction, Abuse, and Misuse

OXYCONTIN® exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing OXYCONTIN and monitor all patients regularly for the development of these behaviors and conditions *[see Warnings and Precautions (5.1)]*.

Life-Threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression may occur with use of OXYCONTIN. Monitor for respiratory depression, especially during initiation of OXYCONTIN or following a dose increase. Instruct patients to swallow OXYCONTIN tablets whole; crushing, chewing, or dissolving OXYCONTIN tablets can cause rapid release and absorption of a potentially fatal dose of oxycodone *[see Warnings and Precautions (5.3)]*.

Source: OxyContin Full Prescribing Information, dated September 2018

Since 2010, as discussed more in Section VI.A, *infra*, OxyContin tablets have incorporated an abuse-deterrent formulation ("**ADF**") that is intended to make the drug both hard to crush and difficult to snort and inject.[49]

[47] *See* OxyContin FPI, at 6.

[48] Because OxyContin is designed to release medicine slowly over time, higher dosages of OxyContin contain a larger amount of oxycodone than immediate-release tablets. *See* February 2002 Senate Hearing, at 15-16.

[49] *See* U.S. Food and Drug Admin., FY2013-2017 Regulatory Science Report: Oral Abuse-deterrent Opioid Products (May 23, 2018), https://www.fda.gov/industry/generic-drug-user-fee-amendments/fy2013-2017-regulatory-science-report-oral-abuse-deterrent-opioid-products; *see also* U.S. Food and Drug Admin., *Abuse-*

B. The FDA Has Continuously Determined That OxyContin Should Remain Available, Striking a Policy Balance Between the Need for Effective Opioid Analgesics and Their Potential for Abuse

"When Congress enacted the Federal Food, Drug, and Cosmetic Act . . . , it charged the [FDA] with ensuring that prescription drugs are 'safe for use under the conditions prescribed, recommended, or suggested' in the drug's 'labeling.'"[50] A drug's labeling includes the "written material that is sent to the physician who prescribes the drug and the written material that comes with the prescription when the drug is handed to the patient at the pharmacy."[51] In the exercise of its authority to approve medications, the FDA "makes careful judgments about what warnings should appear on a drug's label for the safety of consumers."[52] Although the FDA has periodically updated the warnings on labels for extended-release opioids, including OxyContin, the FDA has repeatedly found that opioids like OxyContin are important medications for patients who require them and that, when taken under the care of physicians and in compliance with their instructions and the approved label, they are safe and effective.

The FDA first approved Purdue's New Drug Application for OxyContin in 1995 after a rigorous review process based on 24 studies – six controlled clinical trials, four additional clinical studies, and 14 pharmacokinetic studies involving more than 700 patients. The indication in OxyContin's original label provided that OxyContin was for "the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days." At the time that OxyContin was approved, Purdue and the FDA believed that the controlled-release characteristics of the OxyContin formulation would result in less potential for

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Deterrent Opioid Analgesics (June 11, 2019), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/abuse-deterrent-opioid-analgesics.

[50] *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. __, 139 S. Ct. 1668, 1672 (2019) (citing 21 U.S.C. § 355); *see also Wyeth v. Levine*, 555 U.S. 555, 566-67 (2009) (discussing history and purpose of the FDA).

[51] *Merck Sharp & Dohme Corp.*, 139 S.Ct. at 1668 (citing 21 U.S.C. § 321(m)).

[52] *Id.*

abuse since when taken properly, the drug would be absorbed slowly and there would not be an immediate "rush" or high that would promote abuse.[53] The FDA cited the history of MS Contin, the controlled release formulation of morphine, as supporting its judgment.[54] MS Contin had been approved by the FDA since 1987 without significant reports of abuse or misuse.[55]

OxyContin's original FDA-approved label acknowledged and warned of risks, including abuse, addiction and even death. The original label prominently stated that OxyContin was a Schedule II controlled substance, making clear to providers that OxyContin belongs to the class of drugs with the highest risk of abuse and addiction. In capitalized, bold type, the label warned doctors, pharmacists, and patients against crushing or chewing the tablets and that doing so could **"LEAD TO THE RAPID RELEASE AND ABSORPTION OF A POTENTIALLY TOXIC DOSE OF OXYCODONE."** It also warned that OxyContin "may be habit forming" and that there was a risk of death from acute overdose. And the original label provided, in a section headed "DRUG ABUSE AND DEPENDENCE (Addiction)," that "OxyContin . . . [has] an abuse liability similar to morphine . . . . [and that o]xycodone products are common targets for both drug abusers and drug addicts."

In response to reports in the early 2000s of abuse of the medication,[56] Purdue proactively met and worked with the FDA to strengthen the warnings and precautions sections in OxyContin's labeling. By July 2001, Purdue issued a new label for OxyContin that contained a black box warning highlighting the drug's risks of abuse, diversion, and overdose. The updated

[53] *See* FDA Timeline; *see also* February 2002 Senate Hearing, at 16.

[54] *See* February 2002 Senate Hearing, at 16

[55] *See id.*

[56] *See* February 2002 Senate Hearing, at 16 ("At the time of OxyContin's approval, FDA was aware that crushing the controlled-release tablet followed by intravenous injection of the tablet's contents could result in a lethal overdose. A warning against such practice was included in the approved labeling. FDA did not anticipate, however, nor did anyone suggest, that crushing the controlled-release capsule followed by intravenous injection or snorting would become widespread and lead to a high level of abuse.").

label reiterated instructions not to break, chew, or crush the tablets due to the risk of a potentially fatal overdose and heightened its warnings that doctors should consider the potential for abuse, misuse, and diversion when prescribing.

The FDA's assessment and approval of opioid analgesics, including OxyContin, is far from static.[57] In 2012, for example, Physicians for Responsible Opioid Prescribing ("**PROP**") filed a citizen's petition with the FDA seeking three limitations to the indication for all opioid analgesics: (1) impose a ceiling on the total daily dose that any non-cancer pain patient could receive to the equivalent of 100 milligrams of morphine, (2) limit the duration of treatment for any non-cancer pain patient to 90 days, and (3) restrict the use of opioids for non-cancer pain patients to severe, rather than moderate to severe, pain.[58]

The FDA undertook a 14-month review of PROP's petition. During that time, the FDA held public hearings and workshops, received testimony and thousands of comments from experts and citizens (a majority of which opposed PROP's requests), and assessed the medical literature.[59] Ultimately, the FDA concluded that the scientific evidence did not support the dosing and duration of treatment restrictions that PROP requested.[60] The FDA instead reaffirmed that opioid medications are an effective treatment option for managing pain and rejected labeling changes that would create a distinction between using opioids for "cancer" versus "non-cancer" pain.[61]

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[57] *See* FDA Timeline.

[58] *See* Citizen Petition Letter from Physicians for Responsible Opioid Prescribing ("PROP") to the United States FDA (July 25, 2012), https://www.citizen.org/wp-content/uploads/migration/2048.pdf (hereinafter "PROP Petition").

[59] *See* Letter from FDA to Andrew Kolodny, MD, President of Physicians for Responsible Opioids Prescriptions (Sept. 10, 2013), https://www.regulations.gov/document?D=FDA-2012-P-0818-0793 (hereinafter "FDA Response to PROP Petition").

[60] *See id.* at 11, 14.

[61] *See id.* at 9.

As part of its response to the PROP petition, the FDA required certain labeling changes for extended-release opioid medications, including revising the indication section of the label to underscore that patients in pain should be assessed not only by their rating on a categorical pain intensity scale, but also based on a "more thoughtful determination" of their pain.[62] The FDA implemented this labeling change because it found that continued use of a pain "severity scale" (e.g., mild, moderate, severe) "[did] not sufficiently focus prescribers' attention on their responsibility to make an individualized assessment of patients' needs" in light of risks.[63] The FDA also ordered additional studies on the long-term use of opioids, which are underway.[64] Consistent with this class-wide change, OxyContin's label was modified to state that OxyContin is for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."

In sum, the FDA, to this day, continues to strike a careful balance between the necessity and risks of opioid analgesics.[65] But it is clear that opioid medications like OxyContin "provide clinically significant analgesic benefit, including to address pain for which other analgesics are inadequate."[66] Indeed, OxyContin remains approved by the FDA notwithstanding the Pending

[62] *See id.* at 9; *see also* U.S. Food and Drug Admin., ER/LA Opioid Analgesic Class Labeling Changes and Postmarket Requirements (last visited Sept. 15, 2019), https://www.fda.gov/media/86875/download; *see also* Press Release, U.S. Food and Drug Admin., New Safety Measures Announced for Extended-release and Long-acting Opioids (Sept. 18, 2018), https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm363722.htm.

[63] *See* FDA Response to PROP Petition at 7.

[64] *See id.* at 10-11.

[65] *See* Press Release, U.S. Food and Drug Admin., Statement of FDA Commissioner Scott Gottlieb, M.D., on balancing access to appropriate treatment for patients with chronic and end-of-life pain with need to take steps to stem misuse and abuse of opioids (July 9, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-balancing-access-appropriate-treatment-patients-chronic. ("[T]he FDA remains focused on striking the right balance between reducing the rate of new addiction by decreasing exposure to opioids and rationalizing prescribing, while still enabling appropriate access to those patients who have legitimate medical need for these medicines.").

[66] *See* U.S. Food and Drug Admin., FDA Briefing Document, Joint Meeting of the Drug Safety and Risk Management (DSaRM) Advisory Committee and Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC), at 9 (June 11-12, 2019), https://www.fda.gov/media/127780/download.

Actions. It also remains approved for use and reimbursement by Medicaid and Medicare, as well as by many private insurers.[67] In 2018, at least 43 states and the District of Columbia – all of whom are plaintiffs in the Pending Actions – reimbursed their plan participants for OxyContin prescriptions.[68]

VI. Purdue Has Taken Significant Steps to Reduce the Risk of Abuse of Its Medications

There can be no doubt that opioid misuse, abuse, and addiction has impacted hundreds of thousands of individuals, families, and communities across America. Recognizing the significant public health issue that opioids present, Purdue for a long time has taken substantial steps to reduce the risk of abuse of its opioid medications.

A. Since the 1990s, Purdue Has Devoted Considerable Resources to Developing Abuse-Deterrent Technologies

Purdue spent approximately $1 billion developing opioids with abuse-deterrent properties. As noted above, by crushing the original formulation of OxyContin in direct contravention to the product's warning, OxyContin's extended-release mechanism could be defeated, effectively converting the medicine from a controlled-release tablet into a powder of immediate-release oxycodone that could be snorted or dissolved and injected.[69] Beginning in the 1990s, Purdue started investigating the possibility of combining oxycodone with an antagonist that would counteract the effects of oxycodone if the tablet were to be crushed and injected or

[67] *See, e.g.*, CareSource MyCare Ohio (Medicare-Medicaid Plan) Formulary for 2019, at 10-11 (Sept. 2019), https://www.caresource.com/documents/2019-mycare-formulary-508; Kansas Dep't. of Health & Envir., KanCare Preferred Drug List (Sept. 1, 2019), http://www.kdheks.gov/hcf/pharmacy/download/PDLList.pdf (including OxyContin as a preferred Drug); Nebraska Dep't. of Health and Human Servs., Recommendations, Nebraska Medicaid Preferred Drug List with Prior Authorization Criteria, at 3 (Sept. 4, 2019), https://nebraska.fhsc.com/downloads/PDL/NE_PDL-20190901.pdf.

[68] *See* U.S. Ctrs. for Medicare & Medicaid Servs., State Drug Utilization Data 2018 (July 23, 2019), https://data.medicaid.gov/State-Drug-Utilization/State-Drug-Utilization-Data-2018/e5ds-i36p.

[69] *See* Determination that the OxyContin Drug Products Covered by New Drug Application 20-553 Were Withdrawn for Reasons of Safety or Effectiveness, 78 Fed. Reg. 23273, at 23274 (Apr. 12, 2013), https://www.govinfo.gov/content/pkg/FR-2013-04-18/pdf/2013-09092.pdf).

snorted. In the early 2000s, after reports of widespread abuse and diversion of OxyContin emerged, Purdue significantly increased its efforts to reduce the risk that OxyContin's controlled-release mechanism could be defeated.

These efforts resulted in the abuse-deterrent formulation of OxyContin, which makes the drug both hard to crush and difficult to snort and inject – while still providing patients needed pain relief for 12 hours.[70] In 2007, Purdue requested that the FDA approve the new formulation, which FDA did in April 2010.[71] Soon after receiving FDA approval, Purdue ceased making and selling the original formulation in the United States.[72] In April 2013, based on laboratory, clinical, and epidemiologic data, the FDA determined that reformulated OxyContin was safer than the original and granted reformulated OxyContin the first-ever labeling indicating that the drug was formulated with properties intended to deter abuse.[73]

As part of its efforts to address the opioid crisis, the FDA continues to encourage the development of opioid pain medications that are harder to manipulate and abuse.[74] Although abuse-deterrent products are not abuse-*proof*, the FDA recognizes that they are important innovations that may help reduce the risk of abuse even if that risk cannot be wholly eliminated.[75] In 2013, a group of 48 state attorneys general – including many from states now

[70] *See* U.S. Food and Drug Admin., Ctr. for Drug Evaluation and Research, Application Number 22-272 – Chemistry Reviews (Feb. 18, 2010), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022272s000ChemR.pdf.

[71] *See* Determination that the OxyContin Drug Products Covered by New Drug Application 20-553 Were Withdrawn for Reasons of Safety or Effectiveness, 78 Fed. Reg. 23273 (Apr. 12, 2013), https://www.govinfo.gov/content/pkg/FR-2013-04-18/pdf/2013-09092.pdf).

[72] *See id*.

[73] *See* FDA Timeline; *see also* Determination that the OxyContin Drug Products Covered by New Drug Application 20-553 Were Withdrawn for Reasons of Safety or Effectiveness, 78 Fed. Reg. 23273 (Apr. 12, 2013), https://www.govinfo.gov/content/pkg/FR-2013-04-18/pdf/2013-09092.pdf).

[74] *See* U.S. Food and Drug Admin., Abuse-Deterrent Opioid Analgesics (June 11, 2019), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/abuse-deterrent-opioid-analgesics.

[75] *See id*.

suing Purdue in the Pending Actions –wrote to the FDA praising the FDA for supporting the development of prescription opioids with abuse-deterrent formulations.[76]

B. Purdue Has Been an Active Participant in Efforts to Counter Opioid Abuse

Purdue has consistently worked with government agencies, nongovernmental entities, and law enforcement to design and implement policies and programs to address opioid abuse.

After becoming aware of the growing problem of abuse, misuse, and diversion of OxyContin, Purdue has for example: established the RADARS (Researched Abuse, Diversion, and Addiction-Related Surveillance) system to help provide early signals and valuable data on opioid abuse and diversion;[77] distributed tamper-resistant prescription pads to more than 16,000 DEA prescribers;[78] voluntarily suspended marketing and distribution of the 160 mg OxyContin tablet;[79] retrained the Purdue staff involved in sales;[80] and developed radio frequency identification technology to track medication bottles and protect against counterfeiting and diversion.[81]

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[76] *See* Nat'l Assoc. of Attorneys General ("NAAG") Letter to M. Hamburg, M.D. FDA (Mar. 11, 2013), https://www.naag.org/assets/files/pdf/signons/20130311.Final%20FDA%20Letter.pdf.

[77] *See* U.S. General Accounting Office, Report to Congressional Requestors, Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem, at 40 (2003) (hereinafter "GAO 2003 Report") ("Because reliable data on the abuse and diversion of controlled substance drugs are not available, Purdue developed the Researched Abuse, Diversion, and Addiction-Related Surveillance (RADARS) System, as part of its risk management plan, to study the nature and extent of abuse of OxyContin and other schedule II and III prescription medications and to implement interventions to reduce abuse and diversion."); *see also id.* at 39 ("Purdue's risk management plan includes actions such as strengthening the safety warnings on OxyContin's label for professionals and patients, training Purdue's sales force on the revised label, conducting comprehensive education programs for health care professionals, and developing a database for identifying and monitoring abuse and diversion of OxyContin.").

[78] *See id.* at 41 (noting Purdue's "the distribution of free tamper-resistant prescription pads designed to prevent altering or copying of the prescription").

[79] *See id.* ("Other actions included in the plan that were taken by Purdue prior to submission of its risk management plan include discontinuance of the 160-milligram tablet of OxyContin.").

[80] *See id*.

[81] Aaron Smith, *Keeping tables on Viagra et al: Looking to stop theft, drug industry could switch to RFID within five years*, CNN MONEY (JAN. 26, 2006), https://money.cnn.com/2006/01/26/news/companies/RFID.

Purdue's efforts have continued to the present day. Since 2001, Purdue has undertaken more than 60 initiatives at considerable expense to fight the abuse, misuse, and diversion of prescription opioids. A timeline of representative initiatives and descriptions of those initiatives is provided in Appendix B.

C. In February 2018, Purdue Stopped Promoting Opioid Medications to Prescribers Via a Sales Force

In February 2018, Purdue voluntarily stopped promoting opioid pain medications to prescribers through sales representatives and via other channels, such as in medical journals, and began the process of eliminating its opioid medication sales force. Purdue instead directs all requests for information about its opioid products to its medical affairs department. Purdue no longer has any sales representatives promoting any opioid product to prescribers.

VII. Purdue Accepted Responsibility for Improper Marketing Between 1996 and 2001

The Debtors acknowledge that certain Purdue employees engaged in misconduct between 1996 and 2001 in connection with its marketing of OxyContin, and nothing in the foregoing is intended to minimize those mistakes. Purdue accepted responsibility for the misconduct in 2007 and has since then strived never to repeat it.

Specifically, in 2007, the Purdue Frederick Company, Inc. ("**Purdue Frederick**"), an affiliate of Purdue Pharma, pleaded guilty to misbranding OxyContin, a felony violation of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 ("**FDCA**"), and three senior executives of Purdue Frederick pleaded guilty to strict liability criminal misdemeanor violations of the FDCA. In the plea agreement ("**2007 Plea Agreement**"), Purdue Frederick admitted, among other facts, that between OxyContin's launch in 1996 and June 30, 2001, "certain Purdue supervisors and employees with the intent to defraud or mislead, marketed and promoted OxyContin as less

addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications."[82]

Under the 2007 Plea Agreement with the U.S. Department of Justice ("**DOJ**"), Purdue, through Purdue Frederick and/or Purdue Pharma, paid nearly $600 million in fines and other payments, at the time one of the largest amounts that a pharmaceutical company had ever paid in such a case.[83] The individual executives who pleaded guilty paid over $30 million.[84] Also as part of the 2007 Plea Agreement, Purdue, through Purdue Pharma, agreed to enter into a five-year Corporate Integrity Agreement ("**CIA**") with the Office of the Inspector General of the Department of Health and Human Services ("**OIG**").[85] The CIA required Purdue, among other things, to hire an independent review organization to review promotional and product services, implement policies and procedures that addressed salesforce compensation to ensure that compensation does not motivate individuals to improperly promote Purdue products, and retrain sales staff. Purdue also agreed to submit annual reports to the OIG over a period of five years. From 2007 to 2012, Purdue made regular reports to the OIG. In 2013, Purdue completed the CIA with no significant adverse findings.

Also in 2007, Purdue Frederick, Purdue Pharma, and PPI entered consent judgments with the attorneys general of 26 states and the District of Columbia to resolve allegations – similar to the ones underlying the Pending Actions – that Purdue engaged in unfair and deceptive

[82] *See* Plea Agreement Order, at 2 (Dkt. No. 77), *U.S. v. The Purdue Frederick Company, Inc.*, No. 07-CR-00029 (W.D. Va. July 23, 2007) (hereinafter "Plea Agreement Order").

[83] *See id.* at 6. The fine and payments include: approximately $276.1 million forfeited to the United States; approximately $160 million paid to federal and state government agencies to resolve liability for false claims made to Medicaid and other government healthcare programs; approximately $130 million set aside to resolve private civil claims; approximately $5.3 million paid to the Virginia Attorney General's Medicaid Fraud Control Unit; approximately $20 million paid to fund the Virginia Prescription Monitoring Program; approximately $3 million to Federal and State Medicaid programs for improperly calculated Medicaid rebates; approximately $5 million in monitoring costs; and a $500,000 maximum statutory fine.

[84] *See id.* at 6-7. The individuals were indemnified by Purdue.

[85] *See id*. at 6.

marketing of OxyContin in violation of their respective state consumer protection statutes.[86] Purdue did not admit any wrongdoing as part of these settlements.[87] Purdue paid $19.5 million and agreed to various undertakings, including agreeing to maintain its Abuse and Diversion Detection Program, which required sales representatives to report to Purdue's law department activities suggesting that a healthcare provider might be involved in the abuse or diversion of opioid products and agreeing to submit annual compliance certifications to a multistate group of attorneys general for three years.[88]

Purdue has also settled the following additional lawsuits and investigations brought by state governments related to Purdue's marketing of OxyContin: in 2002, an investigation by the State of Florida that resulted in a payment of $500,000; in 2004, an action brought by the Attorney General of West Virginia for $10 million; in 2006, an investigation by the State of Mississippi for $250,000; in 2015, an investigation by the State of New York for $75,000; and, most recently, in 2016, an action by the Attorney General of Kentucky for $24 million. Other than Kentucky, all these states have again brought actions alleging that Purdue wrongfully marketed OxyContin.

VIII. Today's Opioid Crisis

America faces a profound problem of opioid abuse, misuse and addiction, one that has led to the loss of tens of thousands of lives each year. The Debtors dispute, however, that this highly complex crisis was caused by their marketing of FDA-approved medications or is otherwise attributable to them. The opioid crisis in America is a complex societal problem, driven by multiple factors. As the Massachusetts Department of Public Health recently

[86] *See, e.g.*, Consent Judgment, *Washington v. Purdue Pharma L.P.*, No. 07-2-00917-2, at 2, 14, 18 (Wash. Super. Ct. May 3, 2007).

[87] *See, e.g., id.*

[88] *See id.* at 14.

explained: "[N]o single substance or health care practice is solely responsible for the current opioid crisis. Rather, it's a complex issue with a number of contributing factors."[89]

While prescription drugs continue to be abused, governmental authorities – including the DEA, the CDC, and the National Institute on Drug Abuse – have stated that the principal drivers of opioid overdose deaths today are illicit fentanyl and its analogues.[90] Fentanyl and its analogues can be 50 more potent than heroin.[91] Of the 47,600 opioid-related overdose deaths in 2017, 28,466 involved synthetic opioids, which was a 45% increase between 2016 and 2017, and a tenfold increase in the last five years.[92]

Overall opioid prescriptions, however, peaked in the early 2010s and have been flat or in decline in more recent years, as demonstrated in the following chart. Purdue's OxyContin and Hysingla together comprise only part of the black line at the bottom of the chart below:[93]

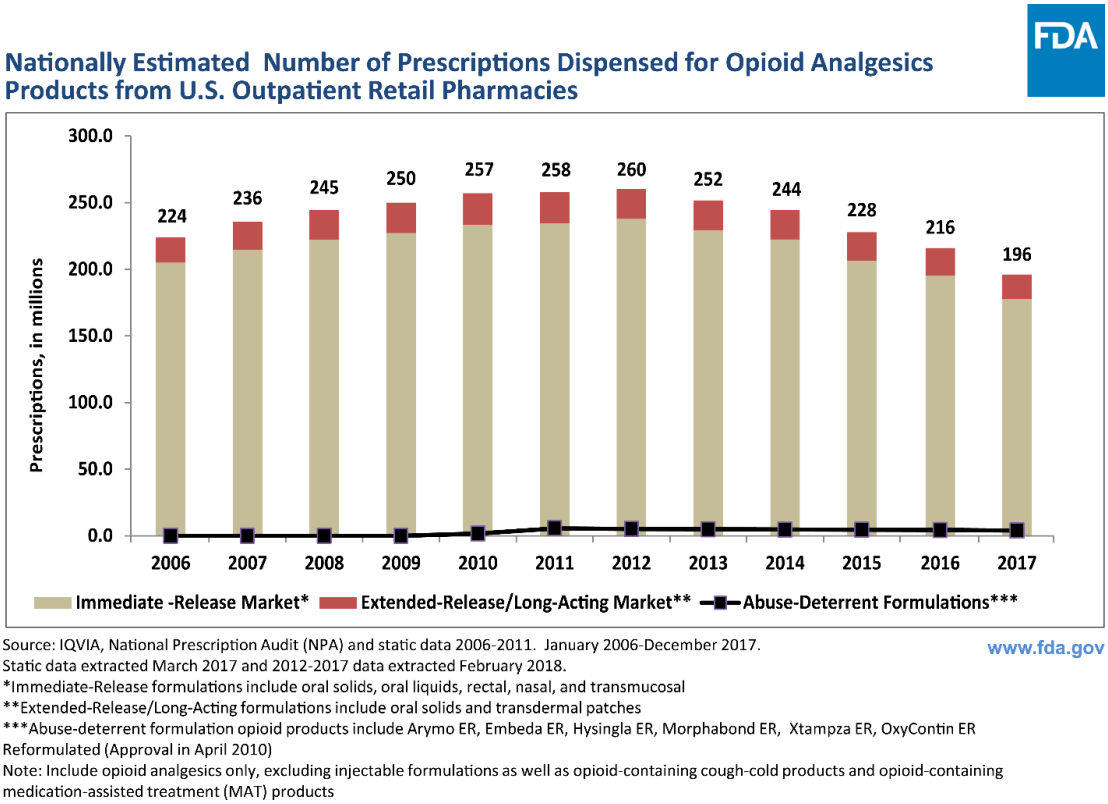
[89] *See* Mass. Dep't of Pub. Health, The Massachusetts Opioid Epidemic: A Data Visualization of Findings from the Chapter 55 Report (Aug. 16, 2017), https://chapter55.digital.mass.gov.

[90] *See, e.g.*, U.S. Ctrs. for Disease Control and Prevention, Drug Overdose Deaths (June 27, 2019), https://www.cdc.gov/drugoverdose/data/statedeaths.html; U.S. Nat'l. Inst. on Drug Abuse, Overdose Death Rates (Jan. 2019), https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates; U.S. Drug Enf't Admin., 2018 National Drug Threat Assessment (Oct. 2018), https://www.dea.gov/sites/default/files/2018-11/DIR-032-18%202018%20NDTA%20final%20low%20resolution.pdf.

[91] *See* U.S. Ctrs. for Disease Control and Prevention, Synthetic Opioid Overdose Data (Apr. 2, 2019), https://www.cdc.gov/drugoverdose/data/fentanyl.html.

[92] *See* Lawrence Scholl et al., Drug and Opioid-Involved Overdose Deaths – United States, 2013–2017, 67 CDC MORBIDITY AND MORTALITY WEEKLY REPORT 1419 at Table 2 (Jan. 4, 2019), https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s_cid=mm675152e1_w.

[93] Presentation, Douglas C. Throckmorton, MD, FDA's Actions to Address the Opioid Epidemic, at 9 (Mar. 14, 2018), https://www.fda.gov/media/112084/download.



IX. The Debtors Face Thousands of Lawsuits in Connection with Their Marketing of Opioid Medications

Against the backdrop of today's opioid crisis, the Defendant Debtors have been named in more than 2,600 lawsuits filed throughout the state and federal court systems. A common set of factual allegations forms the core of these actions: that the Defendant Debtors acted improperly in the marketing and sale of prescription opioid medications, including, principally, OxyContin, and are responsible for the national opioid crisis – notwithstanding that OxyContin represents and has always represented only a tiny portion of the U.S. prescription opioid market.[94] In addition to the Pending Actions, Purdue Pharma has been responding to subpoenas and civil investigative demands issued by various components of the DOJ in connection with criminal and

[94] In addition to the Defendant Debtors, many Pending Actions sue a number of Related Parties – such as former directors (including members of the Sackler Families) or current directors, officers, and entities associated with the Debtors. In fact, recently, an increasing number of these actions have targeted members of the Sackler Families, as opposed to just, or even in lieu of, Purdue. In addition to parties related to the Debtors, the opioid litigations have also named as defendants other manufacturers, distributors or retailers of opioid medications, and others.

civil investigations of Purdue Pharma. Purdue Pharma is engaged in ongoing discussions with DOJ regarding a potential resolution of the investigations.

It is important to note that no court to date has found that any of the Defendant Debtors' conduct caused any of the harms alleged. As explained below, the Debtors believe that these claims are subject to a number of defenses that bar or significantly limit them. But, putting the merits of the litigations aside, the sheer number and scale of the Pending Actions is simply unmanageable. Purdue is a relatively small company with currently fewer than approximately 700 employees. The lawsuits are spread among courts across the country, involve thousands of plaintiffs with differing interests, include a variety of legal claims and theories of damages under multiple states' laws, and are at various procedural stages.

A. The Pending Actions Have Been Brought in Dozens of State and Federal Courts Across the Country

In 2017, the Judicial Panel on Multidistrict Litigation consolidated in the Ohio MDL, for discovery and pretrial purposes, most of the Pending Actions filed in federal court. Since that time, lawsuits against Purdue have continued to be filed at a rapid rate, and the Ohio MDL has grown exponentially. It now includes a large portion – approximately 2,200 – of the Pending Actions.

At the same time, however, there are also hundreds of lawsuits and actions outside the MDL. Over 390 of the Pending Actions are proceeding in dozens of state courts and other forums, as well as courts in the District of Columbia, Puerto Rico and Guam.[95] Although in some jurisdictions – such as Illinois, New York, Pennsylvania, Texas, South Carolina, and Connecticut – actions against the Defendant Debtors have been consolidated in coordinated state

[95] In addition to Pending Actions in the United States, certain of the Defendant Debtors face over ten class actions in Canada, including a governmental class action brought by each Canadian Province alleging similar causes of action to the Pending Actions. Shortly hereafter, Purdue intends to commence an ancillary proceeding with respect to the Debtors' chapter 11 cases in the Ontario Superior Court of Justice (Commercial List) in Toronto, Ontario, Canada.

proceedings, most others are proceeding independently of one another with no coordination. And even the cases currently consolidated in the Ohio MDL, if they were to proceed to trial, would eventually need to be sent back to the districts in which they originated for trial.

In addition, some state government plaintiffs, including Maryland, have commenced administrative proceedings against Purdue to pursue expedited discovery and merits hearings, potentially lasting dozens of trial days.[96] One state filed a motion for leave to file a bill of complaint against the Defendant Debtors and certain Related Parties in the United States Supreme Court, seeking to invoke the Court's original jurisdiction to bypass the lower trial and appellate courts altogether.[97]

B. The Pending Actions Have Been Brought By a Wide Array of Plaintiffs Representing Diverse Interests

Unlike nearly any other prior mass tort litigation, the vast majority of plaintiffs in the Pending Actions – approximately 2,250, or more than 85% – are governmental entities. These governmental plaintiffs include the attorneys general of 49 states, territories and the District of Columbia, as well as thousands of county and municipal governments.[98]

The incentives of these parties are far from aligned. As just one example, there is a significant dispute among the governmental plaintiffs as to which government entities are entitled to bring the claims asserted. The Attorney General of Ohio has questioned the standing of the Ohio municipal plaintiffs in the Ohio MDL trial scheduled for October, and recently filed a petition for mandamus in the United States Court of Appeals for the Sixth Circuit seeking to

[96] *See* Letter from Administrative Law Judge Stephen V. Thibodeau to Counsel, re: Consumer Protection Division v. Purdue Pharma, at 3, *Consumer Protection Division v. Purdue Pharma L.P.*, No. 19-023-311366 (Md. C.P.D. Aug. 6, 2019).

[97] *See* Mot. for Leave to File Bill of Compl., No. 22O151, *State of Arizona v. Richard Sackler* (U.S., July 31, 2019).

[98] *See*, *e.g.*, Suppl. Summons and First Am. Compl., *State of New York v. Purdue Pharma L.P.*, No. 400016/2018 (N.Y. Sup. Ct. Suffolk Cty. Mar. 28, 2019); First Am. Compl., *Commonwealth of Massachusetts v. Purdue Pharma L.P.*, C.A. No. 1884-cv-01808 (Mass. Sup. Ct. Suffolk Cty. Jan. 31, 2019).

dismiss or narrow the claims brought by those entities.[99] Thirteen states and the District of Columbia, as amici curiae, filed a brief in support of the State of Ohio emphasizing that the sheer magnitude of municipal cases undermines the settlement process and amounts to an extraordinary circumstance that is a prerequisite for a writ of mandamus.[100] In addition to standing issues, a substantial majority of the claims of the counties and municipalities seek damages that overlap with or are redundant of the damages sought by the attorney general of their state.

The Pending Actions also include many nongovernmental plaintiffs. Plaintiffs in the Ohio MDL, for example, include dozens of third-party payors, such as hospitals, treatment centers, and insurance companies; over 100 Native American and Alaska Native tribes; over 100 private putative class actions on behalf of various individuals, estates, and entities; and just over a dozen individuals alleging personal injury or wrongful death claims.

C. The Pending Actions Are at Various Procedural Stages, Including Some That Are Set for Trial This October

At the time of this chapter 11 filing, the first MDL "bellwether" trial – *County of Cuyahoga v. Purdue Pharma L.P.*, Case No. 17-OP-45004 (N.D. Ohio) – is scheduled to begin on October 21, 2019. Twelve state court actions have been set for trial in 2020, with more to be set for 2020 and beyond. Dispositive motions have been partially or fully briefed, or decided in approximately 35 cases.

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[99] *See* Pet. for Writ of Mandamus of State of Ohio (Dkt. No. 1), *In re State of Ohio*, No. 19-3827 (6th Cir. Aug. 30, 2019); *see also* Letter from Ohio Attorney General Dave Yost to Judge Dan Polster regarding Plaintiffs' Renewed and Amended Notice of Motion for Certification of Rule 23(b)(3) Cities/Counties Negotiation Class, (Dkt. No. 1973), *In re: National Prescription Opiate Litigation*, MDL No. 2804 (July 23, 2019).

[100] *See* Br. of Amici Curiae of Michigan, Alaska, Arizona, Connecticut, Hawaii, Indiana, Kansas, Montana, Nebraska, North Dakota, South Dakota, Tennessee, Texas, and the District of Columbia in Supp. of the State of Ohio's Pet. For Writ of Mandamus (Dkt. No. 7), *In re State of Ohio*, No. 19-3827 (6th Cir. Sept. 6, 2019).

Discovery is also ongoing. In the Ohio MDL alone, Purdue has produced more than 50 million pages of documents. The Ohio MDL discovery has also included more than 25 depositions of the Debtors' current and former employees, officers, or directors. Substantial additional discovery is expected in the subsequent bellwether or "Track Two" Ohio MDL cases. The state court proceedings, many of which involve very active discovery, are also imposing independent, growing, and unsustainable discovery demands.

D. The Pending Actions Assert a Wide Range of Novel Legal Theories Predicated on Various State and Federal Laws

The specific causes of action asserted against Purdue in the Pending Actions are predicated on both federal and state laws – with variations between the laws of each state. They include: (1) state and federal false claims acts; (2) state consumer protection laws; (3) statutory and common law public nuisance; (4) fraud, fraudulent concealment, deceit, and other willful misconduct; (5) negligence, including negligent misrepresentation, negligence per se, and gross negligence; (6) unjust enrichment; (7) federal and state civil RICO laws, as well as civil conspiracy; (8) state controlled-substances acts; (9) intentional and constructive fraudulent conveyance or transfer; (10) strict products liability; and (11) wrongful deaths and loss of consortium.

E. There Are a Number of Common Legal and Factual Defenses to the Claims Asserted in the Pending Actions

The Defendant Debtors assert a number of common legal and factual defenses that apply to all or most of the cases, which is not surprising given that many of the complaints closely track one another. These defenses include:

- Standing: The Defendant Debtors assert that many of the plaintiffs do not have standing to bring the claims that they asserted.
- Preemption: The Defendant Debtors assert that the FDA's approval of the Defendant Debtors' medications and labeling of those medications preempt state law claims.

- Causation: The Defendant Debtors assert that the causal link between the Defendant Debtors' alleged misconduct (the marketing of OxyContin to healthcare providers) and many of the alleged injuries, for example, a municipal entity having to bear the cost of additional EMS workers to respond to opioid overdoses, including those from illicit opioids, is too remote and separated by too many intervening events for legal liability to attach.

- Statute of Limitations: The Pending Actions include claims that are barred by the applicable statute of limitations.

- Validity of Scientific Evidence: The Defendant Debtors assert that a number of the plaintiffs' experts should be excluded in whole or in part under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

In addition to seeking monetary relief, some of the Pending Actions also seek forms of injunctive relief, such as (but not limited to) requests to enjoin the Defendant Debtors from engaging in future violations of the law, from failing to report suspicious orders, or from engaging in conduct that gave rise to the alleged claims.[101] Certain lawsuits also request that courts compel the Defendant Debtors to establish a fund to "abate" the public nuisance that they allegedly created.[102] Although technically styled as a form of injunctive relief, this is functionally a claim for monetary relief.

As will be discussed in the Preliminary Injunction Motion, the Debtors intend to request that the Court enter an injunction against the Debtors that addresses the past conduct complained of in the Pending Actions. For example, Purdue will agree to be bound to certain restrictions on promotional activity related to the sale of opioids. The Debtors will request this relief to put beyond any doubt that they are not attempting to frustrate governmental functions by seeking refuge in bankruptcy court.

[101] *See* First Am. Compl., *Commonwealth of Massachusetts v. Purdue Pharma L.P.*, Civ. No. 1884-CV-01808 (BLS2) (Mass. Sup. Ct. Suffolk Cty. Jan. 31, 2019); Suppl. Summons & First Am. Compl., *State of New York v. Purdue Pharma L.P.*, Index No. 400016/2018 (N.Y. Sup. Ct. Suffolk Cty. Mar. 28, 2019).

[102] *See* Compl. at 102, *Oglala Lakota Sioux Tribe v. Purdue Pharma L.P.*, No. 18-cv-5021 (D.S.D. Mar. 16, 2018) (requesting that the court "[o]der[] Defendants to fund an 'abatement fund' for the purposes of abating the public nuisance.").

F. No Court Has Ever Found That the Defendant Debtors' Conduct Caused Any of the Harms Alleged by the Plaintiffs in the Pending Actions

To date, not one of the Pending Actions has resulted in any finding of liability against the Defendant Debtors or Related Parties.[103] In fact, the only cases that have been litigated to judgment have been decided in favor of Purdue.[104]

On May 10, 2019, a North Dakota court granted the Defendant Debtors' motion to dismiss (after converting it to summary judgment) in an action brought by the State of North Dakota that asserted causes of action for deceptive marketing practices, consumer fraud, and public nuisance.[105] In a thorough opinion, the court rejected North Dakota's attempt to "essentially hold [Purdue] liable for the impact of opioid overuse and addiction in North Dakota."[106] First, the court dismissed the state's deceptive marketing claims on the basis of federal preemption, holding that those claims were impermissibly based on the "marketing of Purdue's medications for their FDA-approved uses, including for treatment of chronic, non-cancer pain."[107] The court next proceeded to dismiss North Dakota's consumer fraud claims on causation grounds.[108] The North Dakota court found that the state's theory was predicated on "an extremely attenuated, multi-step, and remote causal chain,"[109] and observed that the state's claim that Purdue should be held liable for "the entire opioid epidemic in North Dakota [was]

[103] As discussed below, on March 26, 2019, the Debtors settled an action brought by the Attorney General of the State of Oklahoma without any admission of liability. Consent Judgment as to the Purdue Defendants, *State of Oklahoma, ex rel., Mike Hunter v. Purdue Pharma L.P.*, No. CJ-2017-816 (Dis. Ct. Cleveland Cty. Mar. 26, 2019) (hereinafter "Oklahoma Consent Judgment").

[104] Courts in certain other actions have denied dispositive motions filed by the Defendant Debtors.

[105] *See* Order Granting Mot. to Dismiss, *State of North Dakota ex rel. Wayne Stenehjem v. Purdue Pharma L.P.*, No. 08-2018-CV-01300 (N.D. Dist. Ct. Burleigh Cty. May 10, 2019).

[106] *Id.* at 1.

[107] *Id.* at 15.

[108] *Id.* at 15-23.

[109] *Id.* at 20.

difficult to comprehend."[110] Finally, the court dismissed North Dakota's public nuisance claim because "[n]o North Dakota court has extended the public nuisance statutes [at issue] to cases involving the sale of goods."[111] The court observed that dismissal was particularly appropriate because "[t]he reality is that Purdue has no control over its product after it is sold to distributors, then to pharmacies, and then prescribed to consumers, i.e., after it enters the market."[112] The court denied North Dakota's motion for reconsideration.

Similarly, on January 8, 2019, a Connecticut court granted the Defendant Debtors' motion to dismiss an action brought by various local Connecticut governments.[113] The court emphasized that "courts can't credibly consider cases derived from harms allegedly connected to defendants by lengthy, multifaceted chains of causation that must weigh their conduct while trying to separate that conduct from the myriad of independent factors that make up most broadly defined social crises like . . . opioid abuse."[114] The court dismissed the plaintiffs' claims because "they claim indirect damages that would turn on conjectural analysis of causes and effects."[115]

Although there has not been any finding of liability against the Defendant Debtors in the Pending Actions, the Defendant Debtors' estates have been and will continue to be severely damaged by the crushing weight of mass tort litigation – regardless of their success on the merits. Indeed, liability is not a foregone conclusion, and the plaintiffs would face substantial risks if they proceed to trial. Bankruptcy provides a forum to preserve value, maximize the

[110] *Id.* at 22.

[111] *Id.* at 27.

[112] *Id.* at 26-27.

[113] *See City of New Haven v. Purdue Pharma L.P.*, Dkt. No. X07 HHD CV 17 6086134 S, 2019 WL 423990, at *8 (Conn. Super. Ct. Jan. 8, 2019).

[114] *Id.* at *5.

[115] *Id.* at *5. On January 22, 2019, the City of New Haven appealed the judgment to the Connecticut Appellate Court. Case No. 176490-APPEAL-AC-42507 (Jan. 22, 2019).

estate, and work to achieve a consensual resolution, hopefully through the Settlement Structure outlined below.

X. The Debtors, Their Ultimate Owners, and a Critical Mass of Plaintiffs in the Pending Actions Have Agreed on a Settlement Structure

The Debtors spent the better part of the last year negotiating a global resolution of the Pending Actions. These efforts – which intensified in recent weeks and involved countless phone calls, in-person meetings, and other communications – culminated in an agreement in principal with critical and important constituents on a structure to resolve the Pending Actions that can be effectuated only through these chapter 11 proceedings.

This Settlement Structure would maximize the value of the Debtors' estates and result in an unprecedented transfer of value to the American people. Under the agreed-upon Settlement Structure, as part of a resolution of the litigation: (1) Purdue's existing shareholders will relinquish all of their equity interests in the Debtors and consent to the transfer of all of the Debtors' assets to a trust or similar post-emergence structure for the benefit of claimants and the U.S. public, "free and clear" of Purdue's liabilities to the fullest extent permitted by law; (2) Purdue's existing shareholders will engage in a sale process for their ex-U.S. pharmaceutical companies; and (3) Purdue's existing shareholders will contribute an additional $3 billion over seven years (in addition to 100% of the value of all 24 Debtors), with the hope of substantial further contemplated contributions from the sales of their ex-U.S. pharmaceutical businesses.

This Settlement Structure has the strong support of key constituencies that represent a sizable portion of this country's citizens. These include no fewer than 24 state attorneys general and analogous officials from five U.S. territories. In addition, the Settlement Structure has the backing of the Plaintiffs' Executive Committee (PEC) and Co-Lead Counsel in the Ohio MDL. The PEC is the court-appointed claimants' leadership team in the Ohio MDL that is charged with

coordinating and organizing the various plaintiffs and litigation tracks.[116] It comprises attorneys at law firms that collectively represent over 1,000 counties, municipalities (including cities, towns, and villages), Native American tribes, individuals, and third-party payors. Among these plaintiffs are some of the nation's most populous cities and counties that together with the supporting states and territories comprise well over half of the country's population.

XI. The Alternative to the Consensual Resolution Envisioned by the Settlement Structure Is Chaotic, Value Destructive and Unsustainable Litigation

Having expended untold effort and having made immense progress towards a global resolution, the Debtors and supporters of the Settlement Structure now find themselves at a critical juncture. Implementing the Settlement Structure through these chapter 11 proceedings is the only sensible way forward because continued litigation of thousands of Pending Actions to judgment and through appeals outside of bankruptcy benefits no one. Indeed, continued litigation threatens the success of these chapter 11 proceedings and will only result in the substantial depletion of the Debtors' assets that would otherwise be available for distribution to appropriate stakeholders.

A. The Pending Actions Are Depleting the Debtors' Financial and Operational Resources and Cannot Be Permitted to Continue

Continued litigation of the Pending Actions threatens to significantly erode estate value for at least three reasons.

First, the cost of simultaneously litigating more than 2,600 actions in dozens of state and federal courts around the country is staggering. In the first six months of this year, Purdue Pharma paid approximately $63 million for legal representation, expert fees, and other expenses

[116] *See* Renewed Mot. to Approve Co-Leads, Co-Liaisons, and Executive Committee (Dkt. No. 34), *In re National Prescription Opiate Litigation*, MDL No. 2804 (N.D. Ohio Jan. 3, 2018); Marginal Entry Order Granting Mot. to Approve Co-Leads, Co-Liaisons, and Executive Committee (Dkt. No. 37), *In re National Prescription Opiate Litigation*, MDL No. 2804 (N.D. Ohio Jan. 4, 2018).

directly in connection with the Pending Actions, and is forecasted to spend $121 million by the end of this year. This amount notably does not include, legal fees incurred in the ordinary course of business, legal and other professional fees incurred in connection with preparing for these chapter 11 proceedings, and indemnification costs for current and former directors, officers, employees, or others. All told, Purdue Pharma is projected to spend approximately $263 million on legal and related professional costs in 2019, which constitutes Purdue Pharma's largest operating expense by far. And litigation costs would only be increasing in 2020 and beyond as more and more of the Pending Actions are slated to proceed to advanced stages, including trial. The Settlement Structure would transfer the entirety of Purdue's value to a post-emergence vehicle for the benefit of claimants and the American public, while continued litigation would only serve to divert massive resources – that could otherwise benefit the American people – to lawyers and professionals.

Second, the Pending Actions are a significant drain on the Debtors' human capital and are disruptive to the Debtors' day-to-day operations. Purdue Pharma has drastically cut its number of employees by approximately 67% since 2017. Many of Purdue's remaining employees, including management, spend an enormous amount of time and effort meeting the demands of litigation, which necessarily results in distraction from their core business responsibilities. Employees have spent large amounts of time preparing for depositions and being deposed, devoted countless hours responding to litigation-related requests for information, and otherwise expended significant time and resources participating in the development of the Defendant Debtors' legal defenses.

Third, the Pending Actions have caused or exacerbated operational challenges facing the Debtors. A variety of vendors, suppliers, and other entities necessary to the Debtors' business

operations, alarmed by the potential impact of the Pending Actions, have attempted or threatened to end or change their relationships with the Debtors. For example, negative public sentiment led multiple financial institutions to refuse to work with Purdue, requiring management to spend precious time – for months – securing replacement services.

The Pending Actions, with their attendant drain of financial, human, and operational resources, threaten the Debtors' survival to the detriment of all potential stakeholders, including the plaintiffs in the Pending Actions. As detailed above, this litigation drain is occurring in an environment in which Purdue's sales have deteriorated significantly. As a point of comparison, in 2010, Purdue Pharma generated opioid-related sales of $2.2 billion. By 2018, that number had dropped over half to $975 million. Further material declines are predicted through 2023.

B. A Case-by-Case Approach to Resolving Claims Against the Debtors Is Neither Sustainable nor Equitable

Putting aside the costs associated with the Pending Actions, litigating the massive number of claims in the civil system makes little sense. The Defendant Debtors' settlement of the opioid-related claims asserted by the Attorney General of the State of Oklahoma ("**Oklahoma Settlement**") earlier this year exemplifies this. Although in some ways the Oklahoma Settlement models a negotiated resolution that both resolves the Defendant Debtors' liability and contributes meaningfully to the fight against the opioid abuse epidemic – including by funding a national center for addiction studies and treatment[117] – it also draws into sharp relief the pitfalls and inequity of resolving litigation on a one-off basis outside of bankruptcy.

The amount of the Oklahoma Settlement is not representative of the value of other claims in the Pending Actions and cannot be extrapolated to establish the overall value of those claims.

[117] Under the Oklahoma Settlement, Purdue contributed $175 million and opioid addiction treatment drugs with a market value of $20 million, while the Sackler Families (who were not defendants) will further contribute $75 million for the settlement over a number of years. Proceeds from the Oklahoma Settlement will be used to fund a national center for addiction studies and treatment.

On the contrary, it demonstrates the inherently inequitable nature of piecemeal litigation and settlement, which rewards those claimants who (by chance, fiat, or state law) have their cases scheduled for trial first. That is because, far from reflecting any fair notion of the Defendant Debtors' liability under Oklahoma law, the amount of the Oklahoma Settlement was instead driven in large measure by Oklahoma's first-mover advantage, an arbitrary advantage only amplified by the sheer number of Pending Actions. With new complaints being filed by the day, even settling all currently pending claims in the civil tort system avails little. In fact, not long after the Oklahoma Settlement (which the Debtors believed settled all claims in Oklahoma), a number of Oklahoma political subdivisions contested the effect of the state's settlement on them, and others commenced actions against certain of the Defendant Debtors that assert virtually identical claims.[118] This has only reinforced the Debtors' view that, absent these bankruptcy proceedings, resolution is impossible.

C. Plaintiffs' Attempts to Be First to the Courthouse Continue to Frustrate Resolution of the Pending Actions and Settlement Discussions

A central challenge to resolution of the Pending Actions is that plaintiffs are far from a unified group. As might be expected given the incentives created by piecemeal litigation in the tort system, the plaintiffs continue to jockey for pole position and leverage. For example, a handful of states have chosen to initiate administrative proceedings against the Defendant Debtors. They have initiated these proceedings not because the proceedings are well suited to litigation of issues of this complexity or magnitude (they assuredly are not), but rather because the proceedings provide a potential opportunity to bypass the traditional court system, with its attendant procedural and due process requirements, and speed past other claimants.

[118] *See, e.g.*, Compl., *Bd. of Cty. Comm'rs. of Grady Cty. v. Purdue Pharma L.P.*, No. CJ2019-12 (Dist. Ct. Grady Cty. Okla. Jan. 14, 2019).

As discussed more fully below, the Defendant Debtors will be asking that the Court exercise its powers to preserve the estates and to bring order to the unrelenting chaos of this piecemeal litigation by staying the active litigation against the Defendant Debtors and Related Parties so that there can be a fair and efficient process by which to evaluate, and hopefully finalize, the Settlement Structure, and resolve the various plaintiffs' claims against the Debtors.

XII. This Bankruptcy Presents the Only Rational and Feasible Forum for Constructing and Consummating a Global Resolution of the Pending Actions

One of the fundamental purposes of a bankruptcy is to level the playing field among similarly situated creditors to prevent one creditor from racing ahead of others to obtain an unfair advantage.[119] Indeed, it has long been understood that bankruptcy "provides an appropriate vehicle to resolve massive liabilities" because it is "designed to provide equality of distribution to similar creditors in a collective proceeding while ameliorating the devastating effect that a huge liability may have on the worth of a business and, correspondingly, the compensation available to all victims."[120] Recognizing this, many companies have utilized chapter 11 to address massive potential tort liability. These include Johns-Mansville Corporation, A.H. Robins Company, Dow Corning Corporation, Babcock & Wilcox Company, Armstrong World Industries Inc., W.R. Grace & Company, Takata Corporation, Pacific Gas & Electric Company, Insys Therapeutics, Inc., and others.[121] "What emerges from the history of . . . mass tort cases is

[119] *See, e.g., In re Chowaiki & Co. Fine Art Ltd.*, 593 B.R. 699, 720–21 (Bankr. S.D.N.Y. 2018) ("The very purpose of bankruptcy is to protect the interests of all creditors from the actions of individual creditors, to eliminate[ ] strategic costs that would otherwise be associated with a race to the courthouse.").

[120] Nat'l Bankr. Rev. Comm'n, Report of the National Bankruptcy Review Commission, 318-19 (Oct. 20, 1997), http://govinfo.library.unt.edu/nbrc/report/09bmass.pdf.

[121] *See In re Babcock and Wilcox Co*., 250 F.3d 955, 956-57 (5th Cir. 2001); *In re W.R. Grace & Co*., 475 B.R. 34, 65 (D. Del. 2012); *In re Armstrong World Indus., Inc.*, 320 B.R. 523, 524-25 (D. Del. 2005); *In re Dow Corning Corp*., 255 B.R. 445, 462 (E.D. Mich. 2000); *In re A.H. Robbins Co., Inc.*, 88 B.R. 742, 743 (E.D. Va. 1988); *In re TK Holdings Inc*., No. 17-11375 (BLS), 2018 WL 903980 at *1-2 (Bankr. D. Del. 2018); *see also* Riley Griffin and Jef Feeley, *Insys Files for Bankruptcy, Overwhelmed by costs of Opioid Suits*, BLOOMBERG (June 10, 2019); Peter Eavis and Ivan Penn, *The Struggle to Control PG&E*, N.Y. TIMES (Feb. 13, 2019).

the development of a set of tools and procedures that may be used inside Chapter 11 to fairly and efficiently resolve mass tort claims."[122]

Like companies before them, the Debtors here have filed for bankruptcy because bankruptcy is the only viable means of resolving their potential liability in the face of mass tort claims that cannot be resolved anywhere else, and of altering course from the current value-destroying and untenable situation. Although the precise course of this bankruptcy – and the unprecedented circumstances that it presents – will be charted over time under this Court's direction and with input from relevant stakeholders, it is already clear that a number of procedures are available that will move this case toward a successful resolution.

As stated at the outset, the fundamental purposes of these chapter 11 proceedings include halting the drain on the Debtors' estates; centralizing the claims against the Debtors; fairly and efficiently adjudicating those claims; and, hopefully, constructing a confirmable plan of reorganization to implement the Settlement Structure. Bankruptcy has the unique ability to further these objectives and productively orient future negotiations because it is the only forum available that both ensures that similarly situated entities are treated equally and can provide the requisite finality to all stakeholders.

The first step toward this end (after the filing itself and "first day" relief) is the Preliminary Injunction Motion that the Defendant Debtors intend to file in the coming days. That motion will seek to enjoin all active Pending Actions against the Defendant Debtors brought by governmental plaintiffs (to the extent they are deemed not subject to the automatic stay) and all active litigation against the Related Parties. The Preliminary Injunction Motion reflects the recognition that a key reason bankruptcy is an effective forum for resolving mass tort

[122] *See* Douglas G. Smith, *Resolution of Mass Tort Claims in the Bankruptcy System*, 41 U.C. DAVIS L. REV. 1613, 1639 (2008).

liability is because it provides for a stay of related litigation. As this Court is aware, such a stay does not permit defendants to avoid liability. Rather, such a stay permits "the bankruptcy court to centralize all disputes concerning property of the debtor's estate so that reorganization can proceed efficiently, unimpeded by uncoordinated proceedings in other arenas."[123]

In virtually all chapter 11 cases, the immediate automatic stay is sufficient or virtually sufficient to accomplish that task. Where it is not, courts have not hesitated to issue appropriate injunctions that afford debtors the necessary respite to move their bankruptcy cases forward in a productive manner. For example, in the recent bankruptcy of Takata Corporation, the court enjoined actions brought by governmental entities against the debtors under section 105 of the Bankruptcy Code, as well as individual actions against related parties.[124] This injunction was essential to shielding the debtors from destructive multi-front litigation and enabled them to focus their efforts on effectuating the sale of Takata's assets and consummating a consensual plan of reorganization. The injunctions that will be requested by the Defendant Debtors are equally essential here.

The Debtors remain hopeful that some or all of the parties who do not currently support the Settlement Structure – which calls for the entirety of Purdue's assets to be transferred to a trust or other post-emergence structure for the benefit of claimants and the U.S. public, as well a multi-billion dollar contribution from Purdue's ultimate owners – will continue to engage productively and ultimately come to recognize its value. But if those parties insist on continuing to try to push to the front of the line and pursue their own claims to the detriment of all, decades

[123] *See SEC v. Brennan*, 230 F.3d 65, 75 (2d Cir. 2000).

[124] *See* Order Pursuant to 11 U.S.C. § 105 Granting In Part and Denying In Part Debtors' Mot. For A Prelim. Inj. (Dkt. No. 63), *In re TK Holdings Inc.*, No. 17-50880-BLS (Bankr. D. Del. Aug. 22, 2017); *see also* Debtors' Br. in Supp. of Mot. for a Prelim. Inj. Pursuant to 11 U.S.C. § 105(a) (Dkt. No. 3), *In re TK Holdings Inc.*, No. 17-50880-BLS (Bankr. D. Del. July 13, 2017).

of experience have demonstrated that bankruptcy is a proven and efficient vehicle to successfully, rationally, and equitably resolve these issues. And it should not be forgotten that although not a single judgment has yet been obtained against the Debtors in any forum, 100% of these estates is nonetheless "on offer" under the Settlement Structure.

Putting aside the Preliminary Injunction Motion, the next step would be for the Defendant Debtors to initiate the process by which the claims against them are centralized and crystalized in this Court. To facilitate the identification and analysis of relevant claims, the Debtors intend to file a motion to establish bar dates, approve associated proof-of-claim forms, and approve the form and manner of notice to potential claimants.

This, in turn, will allow the Debtors to perform a comprehensive review, reconciliation, and analysis of claims and to identify common issues that may be resolved efficiently through coordinated and/or consolidated proceedings. "One of the major advantages of [bankruptcy] proceedings is that threshold issues that may be dispositive of whole categories of claims can be addressed in a uniform fashion in a single forum. Such centralized resolution of claims is difficult to achieve in the civil litigation system, and has significant benefits for the consistent and efficient disposition of claims."[125] Bankruptcy tools that permit the efficient resolution of claims include: (1) the ability to implement coordinated and cost-effective discovery protocols; (2) the use of omnibus objections and consolidated hearings or trials to allow or disallow claims involving common questions of law or fact;[126] and (3) the ability to craft flexible and efficient mechanisms for valuing claims through claims estimation pursuant to section 502(c) of the Bankruptcy Code.

[125] *See* Douglas G. Smith, *Resolution of Mass Tort Claims in the Bankruptcy System*, 41 U.C. DAVIS L. REV. 1613, 1634 (2008).

[126] *See* Fed. R. Bankr. P. 3007(d)(1), 7042.

As discussed in Section IX.E, *supra*, the Pending Actions raise a number of common issues and defenses – including ones that were found to be dispositive by the Connecticut and North Dakota courts. Although it remains to be seen whether any of these issues will be litigated, it is clear that this Court will have the unique ability to resolve the claims against the Debtors' estates in a uniform manner that avoids duplication, waste, races to the courthouse, and the inequities of disparate outcomes.

The Debtors remain fully committed to the consensual resolution of the claims against them on appropriate terms and are hopeful that, working together with estate stakeholders, they can deliver billions of dollars of value – and 100% of the assets of every single debtor – to address the opioid crisis that continues to harm individuals, families, and communities across the country.

Dated: September 15, 2019
New York, New York

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Proposed Counsel to the Debtors
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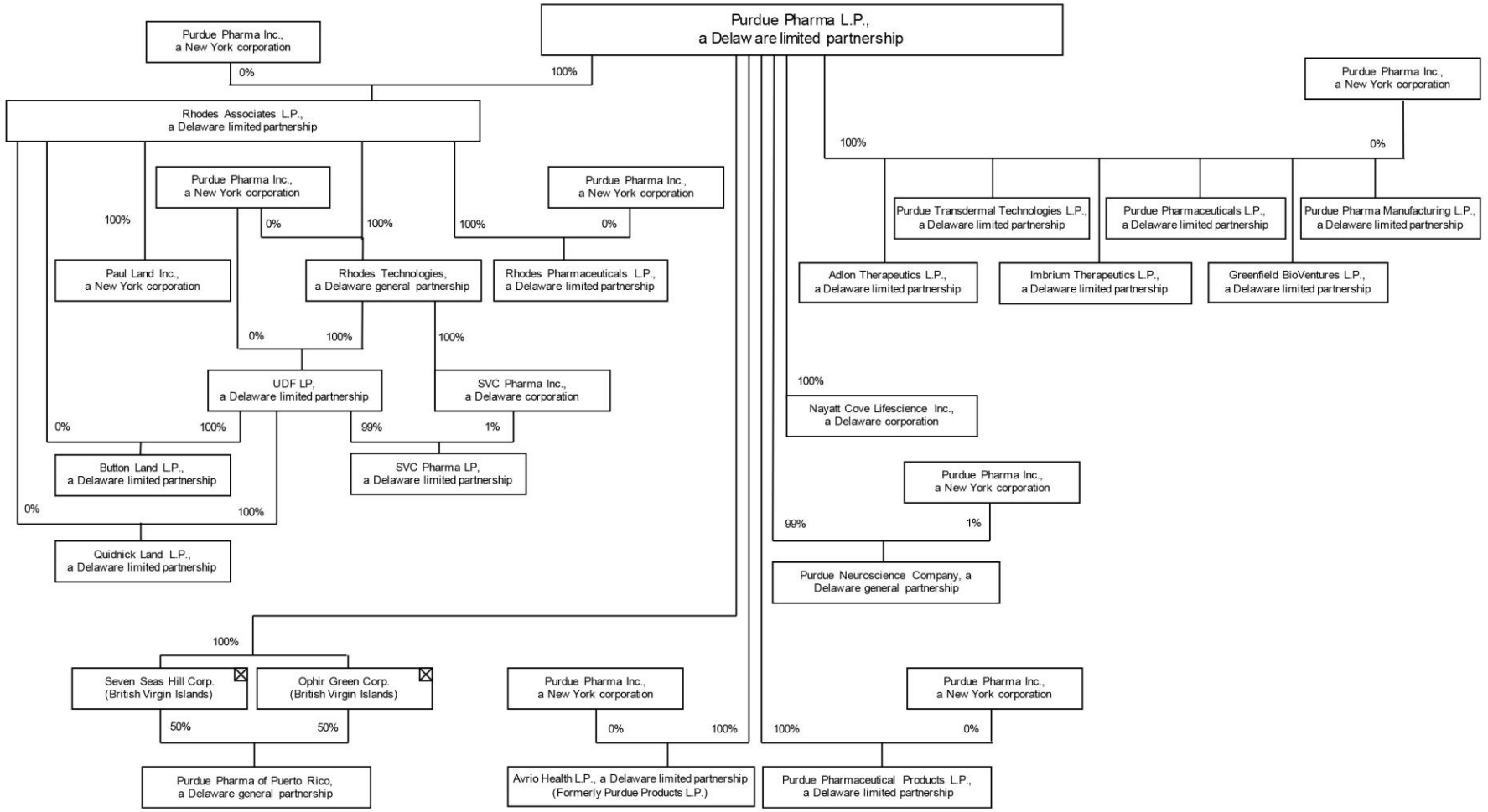
Appendix A:

Purdue Pharma L.P. (and subsidiaries)



Appendix B:

Timeline of Select Initiatives to Fight Abuse

2001

- Purdue developed the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS) system to detect and study abuse, misuse, and diversion on a nationwide basis. Purdue transferred ownership of RADARS in 2006 to not-for-profit Denver Health and Hospital Authority's Rocky Mountain Poison and Drug Center. Purdue transferred the system to an independent third party which allowed pharmaceutical companies and government agencies to more readily access valuable data on opioid abuse and diversion.

- Purdue provided more than $4 million to develop "Painfully Obvious," a prescription drug abuse awareness program for pre-teens, parents, and middle school teachers.

- Purdue began a program to provide tamper-resistant prescription pads at no cost to healthcare professionals. These prescription pads were ordered by more than 16,000 DEA-registered healthcare professionals.

2002

- Purdue voluntarily developed a risk management plan (RiskMAP) in coordination with the FDA to help detect and prevent opioid abuse and diversion.

- Purdue worked with The Governor's Prevention Partnership in Connecticut on substance abuse education, including radio and TV public service announcements. Purdue dedicated more than $550,000 to this effort.

2003

- Purdue developed and distributed an educational campaign on radio, TV, and print media, titled "Empty the Medicine Cabinet," about safe medication storage and disposal.

- Purdue developed RxPATROL (Pattern Analysis Tracking Robberies and Other Losses), the first national database that tracks, analyzes, and provides information on pharmacy crime to law enforcement and retail pharmacies. Purdue continues to maintain this database today.

- Purdue distributed more than 47,000 prescription medication identification cards created by the National Association of Drug Diversion Investigators (NADDI) to law enforcement officers in 210 agencies in 40 states. These cards were created to assist law enforcement in identifying tablets seized during arrests.

- Purdue worked with the University of Minnesota and Clinical Pharmacology Services to develop the Controlled Substances Patterns of Utilization Requiring Evaluation (CS PURE) program for managed care companies to evaluate data.

2004

- Beginning in 2004 and extending through 2016, Purdue provided funding of approximately $2.7 million to support the Partnership for Drug-Free America (later named Drug-Free Kids). Purdue's contribution supported prevention education, a toll-free parent hotline in both Spanish and English, and "Time to Act," a community education program and website for parents, guiding them in step-by-step action if they think or know their child is using drugs or drinking alcohol.

- Purdue spent over $1.35 million to create a community partnership program called "Communities that Care," for prevention outreach on controlled substances issues in 21 communities.

- Purdue supported states that were considering adopting Prescription Drug Monitoring Programs (PDMPs).

- Purdue developed and deployed Radio Frequency ID technology to track medication bottles and protect against counterfeiting and diversion.

2005

- Crime Stoppers USA and Purdue partnered to publicize descriptions of suspects involved in the illegal diversion of prescription medication. Purdue also contributed funding to support financial awards in exchange for information to help solve pharmacy-related crimes.

2008

- Purdue supported the National Community Pharmacists Association's (NCPA) efforts to educate pharmacists and staff about preventing pharmacy crime through grants totaling over $65,000.

- Beginning in 2008 through 2017, Purdue supported the National Association of Drug Diversion Investigators (NADDI) with grants totaling approximately $2.8 million to provide law enforcement with resources to help combat prescription drug abuse and diversion.

2009

- Purdue began supporting Community Anti-Drug Coalitions of America (CADCA) programs to help community groups combat prescription drug abuse.

- Purdue developed and deployed a bottle tracking program to address theft of medication from pharmacies, with more than 500 devices employed in more than 30 states, leading to over 190 arrests and clearance of more than 200 robberies.

- Purdue provided funding to support the U.S. Conference of Mayors' prescription drug abuse awareness campaign.

- Between 2009–2014, Purdue provided $90,000 to support the NCPA Prescription Drug Safety Awards.

2010

- Working with the NCPA, Purdue launched the SafeguardMyMeds.org website and a public service campaign to provide information about safeguarding prescription medicines.

- Between 2010–2015, Purdue supported the National Council on Patient Information and Education and the Substance Abuse and Mental Health Services Administration (SAMHSA) with grants totaling approximately $271,000 to help prevent teen prescription drug abuse, including programs to train parents, educators, healthcare professionals, and other "Teen Influencers."

2011

- Purdue developed RxSafetyMatters.org to provide healthcare professionals, families, and law enforcement with information about curbing abuse and diversion.

- Purdue supported Northeast Communities Against Substance Abuse, Inc., with grants totaling $184,000 in connection with its Teen Influencers program and its local media campaign.

- Purdue provided a $1 million grant to the National Association of Boards of Pharmacy (NABP) to help launch its InterConnect hub, which is designed to enable healthcare professionals to track prescriptions for monitored drugs in other states and help detect "doctor shopping" across state lines, while also protecting patients' privacy.

2013

- Purdue provided the U.S. Conference of Mayors with a $225,000 grant to fund its "Safeguard My Meds Prescription Drug Abuse Prevention Recognition Program". This program awards cities with outstanding local initiatives that have the greatest potential to reduce the misuse and abuse of prescription drugs, particularly among young people.

- Purdue partnered with the National Education Association Health Information Network and provided grants totaling approximately $500,000 to create a resource guide for high school teachers titled, "Rx for Understanding: Preventing Prescription Drug Abuse."

2015

- Purdue supported the National Sheriffs' Association's (NSA) "Saving Lives" program with funding of approximately $850,000 for training on use of and distribution of naloxone overdose kits, with nearly 3,500 doses to 21 states.

2016

- Beginning in 2016, Purdue delivered the U.S. Surgeon General's "TurnTheTideRx" materials to prescribers. These materials outline considerations for healthcare professionals when prescribing opioids for chronic pain.

- Purdue shared the U.S. Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain with over 140,000 healthcare providers to promote appropriate prescribing and use.

- Starting in 2016, Purdue shared CDC Tear Sheets on "Prescription Opioids: What You Need to Know" and "Risk of Addiction, Abuse, & Misuse of Opioids" with prescribers.

- Purdue provided a $3.1 million grant to form a public-private partnership with the Commonwealth of Virginia to enhance its PDMP and the use of data within electronic health records.

- In 2016, Purdue entered into a two-year collaborative research partnership with the University of Oklahoma in connection with a fellowship to study prescription drug use and overdose deaths in the Medicaid population, with funding of more than $215,000.

- In partnership with University of Nebraska, Purdue supported scholarships totaling approximately $254,000 over three years for nine students in the area of pain research.

- Since 2016, Purdue has been working with Geisinger Health System in Danville, P.A., on a study of interdisciplinary pain treatment involving wearable technology, spending approximately $1.2 million.

- Purdue partnered with North Carolina organizations Project Lazarus — a non-profit providing training and technical assistance to communities and clinicians addressing prescription medication issues — and Safe Kids North Carolina to support state-wide medicine disposal activities and conduct research to evaluate the impact of community-based prevention programs on opioid-related overdoses, abuse, and diversion, spending approximately $600,000.

2017

- Since 2017, Purdue has collaborated with the National Institutes of Health (NIH) and the National Institute on Drug Abuse (NIDA) on a public-private partnership as part of the

"Helping to End Addiction Long-term" (HEAL) initiative to advance treatments for opioid use disorder and non-opioid, non-addictive pain medications.

- Purdue became a proud member of the Prescription Drug Safety Network, supporting efforts to bring prevention education created by EVERFI to high school students in over 200 high schools by 2020, spending $1.8 million on this effort between 2017 and 2020.

2018

- Purdue supported the Connecticut Prevention Network with a $400,000 grant for parent and student prescription drug abuse prevention efforts.

- Purdue supported Tyler's Light Foundation, an Ohio-based drug awareness and education organization, with a grant for substance abuse awareness and youth prevention education.

- Purdue supported the NADDI with $1.77 million grant to launch National PDMP Enhanced Data Exchange (NPEDE) in four to five pilot states in conjunction with data and analytics solutions provider Appriss.

- Purdue supported the pregnancy recovery pilot program at The University of Pittsburgh Medical Center's Magee-Womens Hospital with a $175,000 grant.

- Purdue supported Triangle Residential Options for Substance Abusers (TROSA), a North Carolina-based treatment program, with a $10,000 grant.

- Purdue supported the University of Delaware's research intervention for new mothers in substance use recovery with a $50,000 grant.

- Purdue supported To the Moon and Back, a Massachusetts organization that provides support for families of children who were born opiate dependent.

- Purdue provided grants to the Connecticut Child Guidance Center in connection with the organization's mobile prevention education.

- Purdue funded youth-focused recovery outreach and community teams in Hamden, Conn., spending approximately $715,000 over three years.

- Purdue supported Ironton/Lawrence County Ohio's Pay for Success (Recovery to Workforce) Model with a grant of approximately $1.5 million over three years.

- Purdue provided a $3.42 million grant to Harm Reduction Therapeutics to advance the development of its low-cost, over-the-counter naloxone nasal spray.

- Purdue provided financial support to New York's "Keep It Moving" for 2,400 naloxone cases and kit contents. The non-profit provides naloxone education and training in the community.

- Purdue provided $150,000 to Innovative Support to Emergencies Diseases and Disasters ("InStedd") for countywide solutions for treatment and recovery in four focused geographic areas.

- Purdue gave $1 million to the Substance Use Disorder Residential Services Treatment Facility in Indiana.

- Purdue gave $50,000 to the Great Circle Academy Recovery School in Missouri.

- Purdue supported Generations United with a $100,000 grant to provide prevention information and education to grant families affected by opioid and substance abuse.

- Purdue provided support to Marshall University to research a translational model for neonatal abstinence syndrome.

- Purdue provided a $125,000 grant to the Indiana Chamber of Commerce Foundation for a "Recovery to Workforce Program" collaborative initiative.

- Purdue provided grants to the Institute for Excellence in Government — a Massachusetts-based non-profit focused on supporting state and local governments — for data analytics regarding overdose.

- Purdue provided grants to the "Ready to Work" program at Pacific House, a men's shelter in Stamford, Conn.

- Purdue supported the Governor's Prevention Partnership in Connecticut with a $50,000 grant to help fund the "Shift the Dialogue to Prevention for Middle School Youth" initiative.

2019

- Purdue provided a $267,000 grant for Tennessee's Renewal House to support a "Recovery to Work" program for women.

- Purdue began accelerating the development of an opioid overdose reversal agent, committing to spend approximately $10+ million on research between 2018 and 2020. On March 13, 2019, Purdue announced that the FDA has granted Fast Track designation to nalmefene hydrochloride (HCl) injection, the company's investigational opioid antagonist for the emergency treatment of known or suspected opioid overdose. On June 6th, the company announced the initiation and first participant enrollment in a Phase 1 clinical study that will examine pharmacokinetic properties of the nalmefene injection. As part of Purdue's commitment to advancing meaningful solutions to address the opioid crisis, the company will work to bring forward this option with the commitment not to profit from any future sales of this drug.

- Purdue supported Domus Kids — a non-profit supporting struggling students in the Stamford, Conn. area — to provide access to trauma scores and other data for their middle and high school students in Alternative Charter Schools.

- Purdue provided a $50,000 grant to the City University of New York's Research Foundation for the "Workforce Development and Continuing Education Recovery Peers Internship Fund" initiative in the Bronx, N.Y.

OTHER

- Purdue uses comprehensive anti-diversion safety and surveillance processes to track shipments from manufacturing plants.

- Purdue has provided approximately 1.2 million placebo tablets to over 1,000 law enforcement agencies since 2004.

- Purdue has spent approximately $1 billion to develop opioids with abuse-deterrent properties.

- Purdue has frequently conducted and supported discovery research to develop non-opioid pain medications, spending approximately $400 million from 2000-2014. In January 2019, Purdue forged a partnership with Alivio Therapeutics to leverage the company's inflammation-targeting technology to develop a non-opioid pain treatment.